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December 8, 2020

### **VIA ECF**

Honorable Joel Schneider  
United States Magistrate Judge  
U.S. District Court - District of New Jersey  
Mitchell S. Cohen Building & US Courthouse  
1 John F. Gerry Plaza, Courtroom 3C  
4th and Cooper Streets  
Camden, New Jersey 08101

Re: IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS  
LIABILITY LITIGATION  
Civil No. 19-2875 (RBK/JS)

Dear Judge Schneider:

Please accept this letter on behalf of the Plaintiffs in advance of the upcoming December 9, 2020 status conference.

### **1. API and Finished Dose Manufacturing Defendants' Insurance and Indemnification Disclosures**

On May 6, 2019, the Court ordered the API and Finished Dose Manufacturers ("Manufacturer Defendants") to produce all "insurance information required to be produced pursuant to Fed.R.Civ.P. 26(a)(1)(A)(iv)." ECF 98. Under that Rule, Defendants are required to disclose "any insurance agreement under which an insurance business may be liable to satisfy all or part of a possible judgment in the action **or to indemnify or reimburse** for payments made to

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satisfy the judgment.” Fed. R. Civ .P. 26(a)(1)(A)(iv). The Court also issued an Order, including the requirement that the Manufacturer Defendants must “identify all applicable primary and excess/umbrella insurance policies **responsive to Fed. R. Civ. P. 26 (a)(1)(A)(iv)**. The identification shall include all named and additional insureds, dates of policy, and policy limits. Defendants shall produce the Declaration page of each policy and, if requested, a copy of the complete policy.” ECF 120. The Order required the Manufacturer Defendants to “produce all Reservation of Rights and declination letters regarding their coverage demands.” *Id.* The Covered Defendants “have a continuing obligation to supplement their insurance disclosure without the necessity of a formal request to produce.” *Id.*

Beyond the Orders specifically addressing production of insurance information, the failure to produce indemnification agreements would leave a big hole since we know that there are indemnification agreements in place between and among at least some of the parties. These agreements clearly come within the scope of Rule 34 RFP to the manufacturers, #6, which very broadly states: Produce all agreements, contracts, or licenses that the answering defendant is a party to, with regard to (1) the manufacturing process, (2) testing for bioequivalence, purity, or contamination, (3) quality assurance, (4) risk assessment, (5) medical and clinical assessments of bioequivalence, purity, or contamination, (6) regulatory activities, (7) communications with regulatory agencies, (8) production, (9) distribution, (10) packaging, (11) sale, (12) marketing, (13) communications with private individuals or entities, regarding safety, bioequivalence, purity, contamination, and pricing, and (14) procurement of components or ingredients, with regard to valsartan and/ or its ingredients.

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On November 17, 2020, Plaintiffs informed the Manufacturer Defendants that they were requesting any indemnification agreements that they are party to, relevant to this litigation. On December 4, 2020, the Manufacturing Defendants agreed to check “as to whether there are any updates to our prior disclosures,” and produce such documents. However, they claimed that they were not required to produce their indemnification agreements, and they have maintained this position.

Plaintiffs request an order explicitly requiring the Manufacturing Defendants to produce any indemnification agreements that they are party to, related to this litigation. The contractual arrangements for indemnification are clearly relevant and probative, and they will help to fill in the picture of what agreements exist between and among the defendants, and the scope and nature of their corporate relationships. The relevance of this information is not only established by the need for production of full insurance related information, and the terms of RFP #6 set forth above, but also by the 30 b 6 topic addressing indemnification payments in part (using Aurobindo as an example): “All credits, indemnification, refunds, and/or penalties paid or provided by or to Aurobindo (i.e. to/from customers, regulatory agencies) in connection with the nitrosamine contamination of Aurobindo’s valsartan API and finished dose.” Thus, the agreements and tracking of all the payments thereunder has been requested. Finally, the first round of document requests applicable to the retailers and wholesalers also includes a request (#21) for any such indemnification agreements. In order to provide complete information, the manufacturers should produce their indemnification agreements as well.

## **2. Torrent’s Waiver of Designations**

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On October 27, 2020, Plaintiffs wrote to Torrent's counsel challenging its designation of the following five documents as confidential or restricted confidential pursuant to Paragraph 20 of the Court's Confidentiality and Protective Order.

- (1) TORRENT-MDL2875-00100153: An email chain between Torrent and one of its customers regarding the now public recall of Torrent's valsartan.
- (2) TORRENT-MDL2875-00006097: An email chain between Torrent and AmerisourceBergen regarding the distribution of Torrent's products.
- (3) TORRENT-MDL2875-00100222: ZHP's notification to Torrent as to what it should do with valsartan manufactured using the TEA process.
- (4) TORRENT-MDL2875-00006126: An email chain concerning hyperlinks to public websites regarding Torrent's valsartan recalls.
- (5) TORRENT-MDL2875-00072713: An email chain regarding the now public recall of Torrent's Valsartan.

(Ex. A hereto).<sup>1</sup> On November 10, 2020, Torrent replied and advised that it was "standing on its confidentiality designations." Plaintiffs then replied and further explained that "[p]er the Confidentiality and Protective Order, after receiving Plaintiffs' objections, a Producing Party 'shall state with particularity the grounds for asserting that the document or information is CONFIDENTIAL or ATTORNEYS' EYES ONLY.'"

On November 11, 2020, Torrent gave the following justifications for its confidentiality designations:

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<sup>1</sup> Exhibit A is replaced by a placeholder document in the ECF filing at Torrent's request, since Torrent continues to maintain that the documents are entitled to be maintained as confidential despite the expiration of the deadline to take definitive steps to maintain the designations per the terms of the Protective Order. At Torrent's request the documents are not publicly filed, but are being provided directly to the Court.

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- 1) TORRENT-MDL2875-00100153: Although the fact that there was a recall is public, Torrent's email communications with customers regarding that recall are not.
- 2) TORRENT-MDL2875-00006097: Communications with AmerisourceBergen notifying them of the FDA's decision are not public.
- 3) TORRENT-MDL2875-00100222: ZHP's notification to Torrent regarding the recall is not a public document.
- 4) TORRENT-MDL2875-00006126: Though the hyperlinks may lead to public websites, the communications containing those links are not public.
- 5) TORRENT-MDL2875-00072713: Communications concerning the recall are not public, even though the fact that there was a recall is public.

*Id.* During the parties' meet and confer on November 13, 2020, Torrent further explained that if a document was not publicly available, for example via "Google," then Torrent considered the document confidential. During the subsequent meet and confer on December 8, 2020, Torrent reiterated that the documents are non-public and "sensitive," and thus entitled to be designated as confidential. Plaintiffs explained on each occasion that Torrent's definition of documents entitled to confidentiality was incorrect, and that Plaintiffs maintained their challenge to these confidentiality designations.

On December 3, 2020, Plaintiffs emailed Torrent noting that "[p]ursuant to the Court's Confidentiality and Protective Order, the proponent of a 'designation being challenged shall present the dispute to the Court initially by telephone or letter, in accordance with Local Civil Rule 37.1 (a)(1), within twenty-one (21) days of the date when the Producing Party's written response is dated,'" and "[f]ailure to request said conference, or to file the motion shall operate

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as a waiver of the disputed designation.” Given Torrent’s failure to notify the Court of an ongoing dispute regarding these confidentiality designations as provided by the Order, the above listed documents were automatically de-designated as of December 3, 2020. Plaintiffs consequently requested that Torrent utilize the five de-designated documents as exemplars, and “to de-designate all documents similar to these now de-designated documents,” and “advise when you are available to meet and confer on implementing a process to do so.”

Four days later, Torrent sought to extend the process. Torrent’s counsel indicated that it wanted time to reach out to its client to discuss “applicable Indian law.” However, Torrent did not mention Indian law during the parties’ meet and confer, and Indian law cannot be remotely relevant to the confidentiality of the documents at issue. On December 8, 2020 Torrent’s counsel confirmed that they had not confirmed that there was an issue pursuant to Indian law, they just wanted additional time to determine if there was an issue. Plaintiffs also advised of their position that the “Confidentiality and Protective Order does not allow a designating party to unilaterally extend deadlines based on its own inability to confirm the propriety of its designations.” Plaintiffs consequently ask the Court to confirm the de-designation of the five challenged documents and order Torrent to de-designate all similar documents.

On December 8, 2020, Torrent advised that it intends to defend the designations on the five documents as issue, despite the terms of the Protective Order. Torrent also advised that it will not agree to use the documents as exemplars to guide it in de-designating similar documents, claiming that it cannot feasibly do so, but rather insisted that Plaintiffs will have to challenge every document, one by one.

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In addition to the fact that the documents have been de-designated per the terms of the Order, there is no substantive basis to maintain the documents as confidential. On their face, the documents do not fit the definition of documents entitled to confidentiality as they do not contain, “proprietary, trade secret and/or highly sensitive commercial information.” (See Paragraph 9B). In addition, the documents that were communicated with other entities were not maintained as confidential. (See Paragraph 5, 10(d)).

This Court has addressed the standards to maintain confidentiality designations, making clear that the defendant’s classification of documents as confidential is of no moment, nor is the size of the document production, or potential embarrassment or damage to the defendant’s reputation. *In Re: Benicar*, 2016 WL 266353 at \*3 (D.N.J. 2016). In that case the defendants were relying on the terms of the Stipulated Discovery Confidentiality Order, which is quite similar to the one at issue here. *Id.* This Court also emphasized the requirement under the Local Rules for the party seeking to maintain the designation to make a “particularized showing” to establish a “clearly defined and serious injury,” which cannot be done here. *Id.* at \*4, citing *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3<sup>rd</sup> Cir. 1994).

Most important here, with “matters of legitimate public concern,” and more particularly with, “information important to public health and safety,” confidentiality is disfavored. This is in fact the critical factor in these circumstances. *Id.* at \*4-5, citations omitted. These documents address dangerous contamination of blood pressure medication intended for daily use on a global scale so the public interest in all of the details, including as to how such a disaster could occur is enormous. This paramount interest alone outweighs any argument Torrent might make with regard to the milk toast documents they are inexplicably attempting to maintain as confidential –

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none of which even rise to the level where confidentiality is arguably appropriate in the first instance.

Torrent's refusal to concede that the five documents at issue should be de-designated, and refusal to de-designate other similar documents willingly, needs to be addressed. These documents are so obviously outside of the narrow band of documents arguably entitled to confidentiality that Plaintiffs request relief designed to avoid burdening Plaintiffs and the Court with a steady stream of challenges to facially inappropriate designations. Torrent should be required to go back and re-designate documents as confidential to the extent such designation is appropriate, educated by a decision directing that the over-designation to date be remedied. Based on the narrow criteria permitting designations, and the clear over-designation of documents, this should result in only a tiny part of the production being designated. The alternative is an Order directing Torrent to de-designate all documents that were designated similarly to the exemplars identified by Plaintiffs. In either case, this burden should be placed on Torrent now, before the burdens of confidentiality become a factor in the upcoming depositions, and on further motion practice.

### **3. Status of Meet and Confer Regarding Depositions**

The Court's November 25, 2020 Order directed that, "By December 8, 2021 the parties shall complete fulsome discussions regarding the names, dates, and locations of depositions to be taken starting on January 19, 2021." Unfortunately, those discussions have barely begun, and for some defendants have not even started. One thing Plaintiffs have heard is that the Defendants are still figuring out who to designate and on what topic, and that they have until December 23, 2020 to do so. Plaintiffs look forward to the opportunity to work through the many issues,

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including the deponents, locations, logistics, length of time needed for witnesses (i.e. if translators needed, if a witness is addressing substantial 30 b 6 topics requiring multiple days to address), and others.

#### **4. Defendant's Production Deficiencies and Document Dumps**

The Court Ordered rolling productions beginning in July 15, September 1, October 1, and November 1, 2020, with final production to be completed by November 30, 2020. See April. 20, 2020 Order [D.E.] 416. Plaintiffs, at various CMCs, brought up their concerns that Defendants were not properly abiding by the requirement for rolling productions, and were concerned that they would get an inordinate number of documents produced at the end of the process. The Court made clear multiple times that this would not occur and would not be tolerated. In fact, Defendants acknowledged the Court's position during the August 26, 2020 Status Conference indicating that the Court "has been very clear with Defendants that what Your Honor doesn't want is a document dump in December, and that very clear – or November, and that's very clear to Defendants." See Exhibit B, an excerpt of the August 26, 2020 Status Conference Transcript. Unfortunately, that is exactly what has happened.

Between July 15th and November 6th, ZHP produced approximately 500,000 bates numbers<sup>2</sup> of documents (of which approximately 200,000 were a set of batch manufacturing records). After November 6<sup>th</sup>, 2020, ZHP produced approximately 2.3 million bates numbers of documents. Thus, ZHP produced approximately *82 percent* of its non-core production after

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<sup>2</sup> Due to the fact that many documents were produced as natives, Plaintiffs refer to bates numbers rather than page count, as some multi-page native documents were marked as a single bates number, thus it is not possible to accurately determine the actual number of pages produced.

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November 6, 2020. As of the November 30, 2020, deadline, ZHP has produced a total of 244,061 documents since the beginning of this litigation.

Between July 15<sup>th</sup> and November 1st, 2020 Mylan produced approximately 91,000 bates numbers of documents. After November 1st, 2020, Mylan produced approximately 422,000 bates numbers of documents, of which approximately 320,000 were produced on November 30<sup>th</sup>, 2020. Thus, Mylan produced approximately *82 percent* of its non-core production after November 1, 2020. As of the November 30, 2020, deadline, Mylan had produced 234,566 total documents since the beginning of the litigation.

Between July 15<sup>th</sup> and November 2nd, 2020 Teva produced approximately 98,000 bates numbers of documents. After November 2nd, 2020, Teva produced approximately 355,000 bates numbers of documents. Thus, Torrent produced approximately *78 percent* of its non-core production after November 2, 2020. As of the November 30, 2020, deadline, Teva has produced a total of 157,575 documents since the beginning of this litigation.

Between July 15<sup>th</sup> and November 2nd, 2020 Hetero Labs Limited produced approximately 350,000 bates numbers of documents. After November 2nd, 2020, Hetero Labs produced approximately 880,000 bates numbers of documents. Thus, Hetero Labs produced approximately *71 percent* of its non-core production after November 2, 2020. As of the November 30, 2020, deadline, the Hetero Entities have produced a total of 193,098 documents since the beginning of this litigation.

Between July 15<sup>th</sup> and November 5th, 2020 Torrent produced approximately 155,000 bates numbers of documents. After November 5th, 2020, Torrent produced approximately 376,000 bates numbers of documents. Thus, Torrent produced approximately *70 percent* of its

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non-core production after November 5, 2020. As of the November 30, 2020, deadline, Torrent produced a total of 118,102 documents since the beginning of this litigation.

Aurobindo has only produced approximately 109,000 bates numbers worth of documents total, and Auro Pharma Ltd. has only produced only approximately 31,000 bates numbers worth of documents total. That includes core discovery documents. As of the November 30, 2020, deadline, the Aurobindo Entities have produced a total of 13,059 documents since the beginning of this litigation. Plaintiffs are very concerned about this low volume of production.

#### **Additional Issues with Document Production**

##### ***Improperly Withheld Emails and/or Attachments***

In the recent review of these recent document productions which Plaintiffs have received in the last month, Plaintiffs have observed that three Manufacturer Defendants (ZHP, Mylan and Teva) have withheld from production either the body of emails which withheld relevant and responsive documents that were subsequently produced, or attachments to relevant and responsive emails which were produced, on the basis of “Other Products.” By Plaintiffs’ calculation, productions for these three Defendants account for a total of 636,202 documents. Of those documents, Mylan, Teva and ZHP have withheld a staggering 145,208 of these documents, almost 25% of the Defendants total production.

Moreover, without having conducted an assessment of the metadata associated with all 145,208 documents, Plaintiffs have observed an alarmingly large number of documents which are either about a) Valsartan, b) Nitrosamine contamination of Valsartan or c) the facilities in which these Defendants manufactured Valsartan. Plaintiffs attach at Exhibit C a small sampling

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of some of these documents withheld from production listed by filename which Defendants argue should be withheld from production on the basis that it is about “other products.”

Because of the sheer volume of withheld documents (and how this volume of withheld documents impairs Plaintiffs’ review of these custodial emails), Plaintiffs raised the issue with Mylan, Teva, and ZHP and asked that all withheld attachments or emails be produced in full. *See* Exhibits D, E, F (Pls’ emails to Mylan, Teva, and ZHP). Thus far, Mylan and Teva have both substantively responded. *See* Exhibit G (Mylan’s response to Plaintiffs), and Exhibit H (Teva’s response to Plaintiffs).

As a threshold matter (and important to recognize), both Defendants conceded that a large portion of the documents identified by Plaintiffs should have been produced. Teva conceded 31 of the 80 examples Plaintiffs provided were responsive and should be produced, while Mylan conceded that of the 43 examples of withheld products Plaintiffs identified, Plaintiffs were correct that 14 of these withheld documents should have been produced. *Id.*

Despite clearly withholding documents which they now concede were responsive and should have been produced, both Defendants shift the burden of their own production onto Plaintiffs by arguing Plaintiffs were prejudiced by the improper withholding of emails because those attachments were produced in full in other locations in the production. *Id.* This position is nonsensical. Putting aside the evidentiary issues of trying to establish whether one is actually duplicative of a withheld document, it is not Plaintiffs’ obligation to search through hundreds of thousands of documents to locate duplicative copies of documents in weeks leading up to a witness deposition. It is Defendants’ obligation to ensure that all responsive and relevant

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documents were properly produced in the custodial file of the agreed upon custodians in the first instance.

Mylan further argued that even if a document appeared to be about NDMA or NDEA by the name of the document, Plaintiffs may not necessarily be entitled to it (even though it is attached or included as part of document which Mylan has already deemed to be responsive and relevant), because Mylan represents it is about “other drugs” in Mylan’s product portfolio and “not the valsartan at issue in this litigation.” *See* Ex. F.

The Court’s macro discovery order was clear that Plaintiffs are entitled to all documents about Nitrosamines as they relate to *all the sartans*, not only Valsartan. *See* D.E. 303 at 4 (“[D]efendants shall product all documents reflecting the presence of any nitrosamine in any sartan product. This includes not only Valsartan but Losartan, Irbesartan, Olmesartan and Candesartan”). Plaintiffs ask that the Court order any withheld documents regarding nitrosamines related to these other sartan drugs be produced in full. This is not only applicable to Mylan but relates to the ZHP and Teva productions as well.

Additionally, Plaintiffs ask that the Court require Defendants to conduct a thorough analysis of the 145,208 withheld documents to determine the universe of all documents which were “withheld in error” and to provide an overlay for these documents by the end of the year. Plaintiffs cannot be expected to individually review and challenge 145,000 documents when it is obvious there are large swathes of responsive and relevant documents which have been improperly withheld.

***Use of Personal Email Addresses for Business Communications***

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Plaintiffs have also raised with ZHP the issue of document collection of personal email addresses by ZHP custodians. In their review of the recently produced documents, Plaintiffs have identified at least 4 ZHP custodians who were communicating with personal gmail, hotmail, or yahoo email addresses. *See* Ex. E (Pls' Email to ZHP re Document Production – actual email addresses have been redacted). Furthermore, Jun Du, a ZHP custodian slated to be deposed in the coming months, appeared to be communicating using 6 different email accounts. *Id.* Because it appears as though ZHP was sanctioning use of personal email addresses for business communications, Plaintiffs have asked for a meet-and-confer regarding how this issue is being addressed by ZHP's custodial file collection and whether these documents will be produced by the December 31, 2020, deadline for Chinese Custodial documents. ZHP has responded that it is investigating Plaintiffs' issue, and the Parties will meet and confer this week.

#### **4. Losartan Master Complaints**

On December 18, 2019, the Judicial Panel on Multidistrict Litigation expanded the scope of this MDL to include claims arising out of the purchase or ingestion of losartan and irbesartan. To date, a number of both personal injury and class cases have been filed, though no Long Form Complaints or Short Form Complaints exist. In order to begin to streamline these proceedings, Plaintiffs plan to file Long Form Complaints by January 31, 2021. Plaintiffs further intend to file a proposed, modified Amended Short Form Complaint that incorporates the Long Form Complaints as to all three drugs, as well as any new defendants. Plaintiffs believe this consolidated Amended Short Form Complaint is the most efficient vehicle, as there are already cases on file involving certain plaintiffs who ingested a combination of these drugs (valsartan,

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losartan, and/or irbesartan). Because Fed. R. Civ. P. 19(a), which requires the joinder of any "required party," the Short Form Complaint should be filed as a single action.

**5. Wholesaler Discovery Update**

Plaintiffs met and conferred with Wholesaler Defendants on December 2 about Wholesaler Defendants' document productions and written discovery responses. Wholesaler Defendants committed to getting back to Plaintiffs on several items. Plaintiffs anticipate that any impasse between the parties will be raised at the next CMC.

**6. State Court Litigation**

Plaintiffs continue to request the names of plaintiffs' counsel, and production of the filed pleadings in the state court cases that are pending outside New Jersey, and this has not been provided by Defendants. This will allow Plaintiffs to know who to contact, and to understand the status of those litigations. Plaintiffs hope this information can finally be provided before the status conference.

Thank you for your courtesies and consideration.

Respectfully,

A handwritten signature in blue ink, appearing to read "Adam M. Slater", written over a horizontal line.

Adam M. Slater

## Exhibit A

# Document Placeholder

Exhibit A is replaced by a placeholder document in the ECF filing at Torrent's request, since Torrent continues to maintain that the documents are entitled to be maintained as confidential despite the expiration of the deadline to take definitive steps to maintain the designations per the terms of the Protective Order. Therefore the documents located at TORRENT-MDL2875-00100153, TORRENT-MDL2875-00006097, TORRENT-MDL2875-00100222, TORRENT-MDL2875-00006126, and TORRENT-MDL2875-00072713 have been withheld for public filing, but Plaintiffs will forward the relevant portion of the document to the Court directly via email for in camera review.

## Exhibit B

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

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IN RE: VALSARTAN PRODUCTS  
LIABILITY LITIGATION

CIVIL ACTION NUMBER:  
1:19-md-02875-RBK-JS

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STATUS CONFERENCES  
(Via telephone)

Wednesday, August 26, 2020  
Commencing at 10 a.m.

B E F O R E: THE HONORABLE JOEL SCHNEIDER,  
UNITED STATES MAGISTRATE JUDGE  
THE HONORABLE ROBERT B. KUGLER,  
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

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Proceedings recorded by mechanical stenography;  
transcript produced by computer-aided transcription.

1    **A P P E A R A N C E S : - C O N T I N U E D**

2

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19           Teva Pharmaceuticals USA, Inc., Actavis LLC, and Actavis  
20           Pharma, Inc.

16

17           BARNES & THORNBURG LLP  
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             For the Defendant Mylan and the Joint Defense Group

1 attempting to meet the prioritization. They've identified the  
2 key custodians they want. My understanding is all of the  
3 defendants are front-loading those custodians and plaintiffs  
4 are getting that information. Whatever documents they had  
5 prioritized, they are getting that.

6 And to change the orders that Your Honor has issued  
7 months ago is going to really create a problem for defendants,  
8 and it seems that that is what is happening on every one of  
9 these case management conferences, and of course, we're going  
10 to have three more months of rolling productions and every  
11 month, or every two weeks, plaintiffs are going to say there  
12 are deficiencies, there are problems, things aren't yet  
13 produced. But that is the nature of a rolling production, and  
14 Your Honor has been very clear with defendants that what Your  
15 Honor doesn't want is a document dump in December, and that's  
16 very clear -- or November, and that's very clear to  
17 defendants.

18 I would say that while Mr. Slater is saying to Your  
19 Honor that there are things that are missing, that Your Honor  
20 adhere to the order that you previously entered, which is a  
21 rolling production, prioritize based on plaintiffs'  
22 prioritization without any changes, let us produce our  
23 documents, let's deal with real issues on a biweekly basis and  
24 we'll get to the end of this production in a way that's  
25 satisfactory to plaintiffs and the Court.

## Exhibit C

Bates Number	Custodian	File Name	Justification for Withholding
MYLAN-MDL2875-00264658	Gomas, Antonyraj	Valsartan VST COAs with PSD updated.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00264675	Gomas, Antonyraj	Valsartan Samples NDMA/NDEA analysis.	Withheld – Non-responsive/other products
MYLAN-MDL2875-00264924	Mahanti, Satish	Valsartan API batches- Requested by customers to check NDEA - revised ver 2_21.11.2	Withheld – Non-responsive/other products
MYLAN-MDL2875-00264925	Mahanti, Satish	RE: Valsartan API - NDEA content	Withheld – Non-responsive/other products
MYLAN-MDL2875-00265503	Malki, Reem	Valsartan Tablets 80mg_ForeignSubstancePhoto.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00270209	Abbineni, Jyothibas	valsartan initial chromatography part 1 of 2.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00270210	Abbineni, Jyothibas	valsartan initial chromatography part 2 of 2.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00275540	Anabathula, Venkata	Valsartan API Batches details 03.04.2019.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00276607	Anabathula, Venkata	O-Xylene GC Chromatograms.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00276719	Anabathula, Venkata	Valsartan_Acknowledgement Letter.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00277240	Basade, Imtiyaz	Valsartan_Query.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00277469	Basade, Imtiyaz	Valsartan Ph Eur_Batch size enhancement_16032011.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00277522	Basade, Imtiyaz	Valsartan.xls	Withheld – Non-responsive/other products
MYLAN-MDL2875-00277622	Basade, Imtiyaz	Valsartan_2009-146_Amendment_March 2011.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00295990	MVRBS, Subrahmanyam	Valsartan complaint Investigation report.doc	Withheld – Non-responsive/other products
MYLAN-MDL2875-00295993	MVRBS, Subrahmanyam	Valsartan MOA.PDF	Withheld – Non-responsive/other products
MYLAN-MDL2875-00298847	Nampally, Chandu	O-Xylene MSDS.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00300094	Vasireddy, Srinivas	Valsartan (VST).xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00300139	Vasireddy, Srinivas	Valsartan requirement as per mail dt 09th nov 11.xls	Withheld – Non-responsive/other products
MYLAN-MDL2875-00301231	Gomas, Antonyraj	EMA_N_Nitrosodimethylamine.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00301339	Gomas, Antonyraj	NDMA and NDEA content in Valsartan_AMT Protocol.docx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00344251	MVRBS, Subrahmanyam	Valsartan NDMA & NDEA Validation Report.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00344253	MVRBS, Subrahmanyam	Valsartan NDMA, NDEA, NEIA and NDIA Content by GC-MS AMV Report.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00346773	Prerepa, Sreenivasarao	Valsartan_NDMA_NDEA content Results_AUS.PDF	Withheld – Non-responsive/other products
MYLAN-MDL2875-00347218	Rawjee, Yasir	Valsartan VST VAA.XLSX	Withheld – Non-responsive/other products
MYLAN-MDL2875-00348085	Vaidya, Pradeep	Valsartan Tablet 40 mg 3037498_Analytical Report.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00348145	Vaidya, Pradeep	Valsartan_LC_20180205121120.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00348172	Vaidya, Pradeep	VALSARTAN_GCMS_20180205121402.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00350761	Venkatasagi, Varma	Valsartan_Enantiomer by HPLC OOS 1237682_AVL.DOC	Withheld – Non-responsive/other products
MYLAN-MDL2875-00358255	Venkatasagi, Varma	NDMA & NDEA Study Report - Addendum.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00358256	Venkatasagi, Varma	NDMA & NDEA Study Report.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00368146	Gomas, Antonyraj	RE: Very urgent inquiry for Valsartan from	Withheld - Non-responsive/other products
MYLAN-MDL2875-00369958	Indukuri, Jayababu	Valsartan_NDMA_NDEA content ResultsEU.doc	Withheld - Non-responsive/other products
MYLAN-MDL2875-00376040	Khambete, Makarand	Risk Assessment Report Zhejiang Huahai Pharm. Co. Ltd..pdf	Withheld - Non-responsive/other products
MYLAN-MDL2875-00396580	Prerepa, Sreenivasarao	Valsartan VSD - Lantech Mylan -2018 S2.xlsx	Withheld - Non-responsive/other products
MYLAN-MDL2875-00396581	Prerepa, Sreenivasarao	Valsartan VSD - Lantech Mylan -2015 S2.xlsx	Withheld - Non-responsive/other products
MYLAN-MDL2875-00404968	Abbineni, Jyothibas	Valsartan Quality Analysis.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00405987	Abbineni, Jyothibas	Valsartan # XRD-VSN-REP-146.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00412143	Abbineni, Jyothibas	RE: Valsartan drying - Documents required to send material for trials	Withheld – Non-responsive/other products
MYLAN-MDL2875-00412392	Abbineni, Jyothibas	Valsartan (VST) Cycle time (16MT) as on June15.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00412393	Abbineni, Jyothibas	Valsartan process bmr-ortin.doc	Withheld – Non-responsive/other products
MYLAN-MDL2875-00412394	Abbineni, Jyothibas	Valsartan-turbo drying-HPLC (purity).pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00412395	Abbineni, Jyothibas	Valsrtan analysis.docx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00414750	Abbineni, Jyothibas	Responses to Questions - EMEA-H-A31-1471 - Losartan.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00414751	Abbineni, Jyothibas	Responses to Questions - EMEA-H-A31-1471 - Olmesartan.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00414752	Abbineni, Jyothibas	Responses to Questions - EMEA-H-A31-1471 - Irbesartan.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00415008	Abbineni, Jyothibas	Valsartan rec.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00415145	Abbineni, Jyothibas	Valsiure Citizen Petition 6.13.2019 (FDA-2019-P-2869-0001).pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00415158	Abbineni, Jyothibas	Valsartan Destruction Note.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00415246	Akula, PulleswaraRao	Valsartan VSJ-optical Isomer OOS_CQA comments_26-05-16.doc	Withheld – Non-responsive/other products

Bates Number	Custodian	File Name	Justification for Withholding
MYLAN-MDL2875-00415320	Akula, PulleswaraRao	Valsartan(VSJ) Assay by HPLC_CQA_Review 30112016.doc	Withheld – Non-responsive/other products
MYLAN-MDL2875-00415522	Akula, PulleswaraRao	Valsartan_Enantiomer by HPLC OOS 1237682_AVL.DOC	Withheld – Non-responsive/other products
MYLAN-MDL2875-00423479	Anabathula, Venkata	FW: Valsartan - inclusion of Methanol and Toluene to CEP/DMF	Withheld – Non-responsive/other products
MYLAN-MDL2875-00424447	Anabathula, Venkata	Valsartan Stage-I Protocol (VST-I).pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00424983	Anabathula, Venkata	Valsartan Investigation report-Teva.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00425044	Anabathula, Venkata	Valsartan - Analysis report from EMS.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00425961	Anabathula, Venkata	Valsartan 100000706.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00428910	Anabathula, Venkata	Valsartan_TSE-BSE_declaration.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00428914	Anabathula, Venkata	Valsartan MSDS.PDF	Withheld – Non-responsive/other products
MYLAN-MDL2875-00447843	Basade, Imtiyaz	Nitroso impurities-current status-16042019.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00447954	Bhadane, Sachinkumar	Valsartan AMT Certificate.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00453143	Bird, Cassandra	Valsartan Mylan Global Summary - Rev 01_12NOV2018.pptx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00453550	Bird, Cassandra	Valsartan Press Release 11.20.18 US Valsartan Recall_FINAL.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00468153	Gangula, Narenderreddy	O-Xylene VAA-II.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00468154	Gangula, Narenderreddy	O-Xylene VST-VLN-II.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00471064	Gomas, Antonyraj	Valsartan Commercial Data 2013 - 2018-Batch numbers-Sent-US Mkt-Square.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00471109	Gomas, Antonyraj	Valsartan_NDMA_NDEA content Results_AUS.PDF	Withheld – Non-responsive/other products
MYLAN-MDL2875-00471146	Gomas, Antonyraj	Valsartan API Data nashik recovered solvents.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00471148	Gomas, Antonyraj	valsartan Jadcherla - solvent details.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00471833	Gomas, Antonyraj	Valsartan VSD - Lantech Mylan -2015 Final.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00471836	Gomas, Antonyraj	Valsartan VSD - Lantech Mylan -2018 Final.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00471849	Gomas, Antonyraj	Valsartan Recertified COA's.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00472144	Gomas, Antonyraj	Valsartan HCTZ CBE 30 Supplement Status.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00472550	Gomas, Antonyraj	Valsartan_Mylan Unit 8 Errata.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00472552	Gomas, Antonyraj	Valsartan (VAA) assesment report for all six impurities (Declaration).pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00472625	Gomas, Antonyraj	Nitrosamine Testing Requests.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00507240	Mahanti, Satish	Valsartan API batches- Requested by customers to check NDEA - revised ver 2_21.11.2	Withheld – Non-responsive/other products
MYLAN-MDL2875-00507251	Mahanti, Satish	valsartan_Response-NDEA-Hovid-29112018.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00507414	Mahanti, Satish	Valsartan_182523_US_Teva_10112008.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00507415	Mahanti, Satish	Valsartan_DMF 18253_LoA_Teva_031209.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00507416	Mahanti, Satish	Valsartan_DMF 18253_LOA_Teva_15062010.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00507417	Mahanti, Satish	Valsartan-DMF_18253_LOA_Teva_15062010.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00507419	Mahanti, Satish	Valsartan USP-Reissued LOA-Square pharma.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00509408	Malki, Reem	Valsartan HCTZ Investigation Report 543779 585169 29 04 15 AV.docx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00509576	Malki, Reem	FW: VALSARTAN HCTZ Investigation report and HA communications	Withheld – Non-responsive/other products
MYLAN-MDL2875-00509590	Malki, Reem	FW: VALSARTAN HCTZ Investigation report and HA communications	Withheld – Non-responsive/other products
MYLAN-MDL2875-00514900	Malki, Reem	FW: Valsartan API / FP - data - Odor Complaint	Withheld – Non-responsive/other products
MYLAN-MDL2875-00515164	Malki, Reem	Valsartan_EMA-Mylan_Response-30072018.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00521922	Murthy, GNVS	Valsartan --- Lantech.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00531238	Nadendla, Anjanikumar	Valsartan Data.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00531477	Nadendla, Anjanikumar	Valsartan (VAA-MI) PXRD OOS Investigation Report (PR#1668389).pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00531969	Nadendla, Anjanikumar	Valsartan (VAA-MI) PXRD OOS Investigation Report (PR#1668389).pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00531987	Nadendla, Anjanikumar	Valsartan.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00532175	Nadendla, Anjanikumar	Valsart OOS Report for Amide Impurity (PR#1628577).pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00568472	Venkatasagi, Varma	Valsartan XRD Complaint investigation Report.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00569024	Venkatasagi, Varma	Valsartan (VST-CO) Ethyl acetate OOS (PR#1424235) - 15.03.18.docx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00570181	Venkatasagi, Varma	Valsartan USP _ Specification.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00570791	Venkatasagi, Varma	Valsartan (JP) NMDA Declaration.docx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00570797	Venkatasagi, Varma	Valsartan (JP) NMDA Declaration.docx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00572053	Venkatasagi, Varma	Valsartan recertified COA's.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00572115	Venkatasagi, Varma	Valsartan-Response-Lab Alter-26.10.2018.pdf	Withheld – Non-responsive/other products

Bates Number	Custodian	File Name	Justification for Withholding
MYLAN-MDL2875-00572116	Venkatasagi, Varma	Valsartan_communication to customers_Nov2018.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00572202	Venkatasagi, Varma	Valsartan_batch analysis data_1.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00572206	Venkatasagi, Varma	VALSARTAN_BATCH DATA_20180810200123.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00572209	Venkatasagi, Varma	VALSARTAN_BATCH DATA1_20181116195325.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00572211	Venkatasagi, Varma	VALSARTAN_BATCH DATA_20181116195155.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00572759	Venkatasagi, Varma	Valsartan All Routes 121118.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00572778	Venkatasagi, Varma	Valsartan VST COAs.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00572779	Venkatasagi, Varma	Valsartan VAA COAs with PSD.PDF	Withheld – Non-responsive/other products
MYLAN-MDL2875-00572780	Venkatasagi, Varma	Valsartan VAA COAs.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00572781	Venkatasagi, Varma	Valsartan VST COAs with PSD.PDF	Withheld – Non-responsive/other products
MYLAN-MDL2875-00572991	Venkatasagi, Varma	Valsartan - Batches Manufactured from Mar-2017 (SS-1).xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00572998	Venkatasagi, Varma	Valsartan - Batches Manufactured from Mar-2017 (SS-1).xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00573263	Venkatasagi, Varma	Sartan Detail Spreadsheet_11March2019_v3.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00573436	Venkatasagi, Varma	Valsartan.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00573608	Venkatasagi, Varma	Valsartan Compatability checking.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00573688	Venkatasagi, Varma	Valsartan Dispatch Details.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00573815	Venkatasagi, Varma	Valsartan supplement validation protocol.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00574290	Workman, David	Valsartan Summary 09.27.2018.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00595315	Basade, Imtiyaz	recovered o-Xylene-VST-VAA.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00595474	Basade, Imtiyaz	Valsartan USP_Unit-8.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00595585	Basade, Imtiyaz	Valsartan API	Withheld – Non-responsive/other products
MYLAN-MDL2875-00595593	Basade, Imtiyaz	RE: Valsartan API	Withheld – Non-responsive/other products
MYLAN-MDL2875-00595594	Basade, Imtiyaz	Valsartan CEP suspension notification_16Nov2018.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00597774	Bird, Cassandra	Valsartan, Stericycle Consumer Product Return Jan 28 2019.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00632013	Kasbekar, Uday	Valsartan API Justification report for Nitrosamines.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00633292	Khambete, Makarand	Valsartan tab_3022235_3022236_9M_canada_220115.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00633305	Khambete, Makarand	Valsartan Tablets_160mg_8031419_18.01.15.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00637009	Khambete, Makarand	RE: Valsartan 40 and 80mg Stability water content (Follow up)	Withheld – Non-responsive/other products
MYLAN-MDL2875-00640972	Kolla, Naveenkumar	Valsartan0.6 RRT trend data-.xls	Withheld – Non-responsive/other products
MYLAN-MDL2875-00641038	Kolla, Naveenkumar	Valsartan amino acid imp RRT details.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00641611	Kolla, Naveenkumar	Valsartan batches data 06-05-15.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00641631	Kolla, Naveenkumar	Valsartan_28-10-15.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00641654	Kolla, Naveenkumar	Valsartan (VST) MIP batch data 08.11.15.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00642401	Kolla, Naveenkumar	Valsartan VST Vs VAA advantages.pptx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00642440	Kolla, Naveenkumar	Valsartan basic patent.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00652626	Kupec, Kimberly	Valsartan_HCTZ Tabs 120512.xls	Withheld – Non-responsive/other products
MYLAN-MDL2875-00659611	Kupec, Kimberly	Valsartan-Changes included in response to query- Nov 2018.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00661402	Lotus	Valsartan-HCTZ Image Comparison.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00661511	Lotus	Valsartan_Pending FDA_PO4500091061_01.11.12.xls	Withheld – Non-responsive/other products
MYLAN-MDL2875-00662119	Lotus	Valsartan_US_Amendment_Additional site_May09_Coverletter.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00662255	Lotus	Valsartan_25%.xls	Withheld – Non-responsive/other products
MYLAN-MDL2875-00662256	Lotus	Valsartan Manufacturing Plan 25% - March 2012.xls	Withheld – Non-responsive/other products
MYLAN-MDL2875-00662262	Lotus	Valsartan_25%.xls	Withheld – Non-responsive/other products
MYLAN-MDL2875-00662263	Lotus	Valsartan Manufacturing Plan 25% - March 2012.xls	Withheld – Non-responsive/other products
MYLAN-MDL2875-00663619	Lotus	Valsartan pending FDA release 17.xls	Withheld – Non-responsive/other products
MYLAN-MDL2875-00664547	Lotus	Valsartan Mylan_Valsartan_DK_H_1613_001-003_IB_007_PVAR_IB_BIlf1b1_kvot_2012	Withheld – Non-responsive/other products
MYLAN-MDL2875-00666114	Lotus	VALSARTAN 160-25 mg 30 FILM COATED TABLETS 120021A ALEMBIC-MYLAN-FRA	Withheld – Non-responsive/other products
MYLAN-MDL2875-00668891	Lotus	RE: Valsartan Proposals	Withheld – Non-responsive/other products
MYLAN-MDL2875-00668954	Lotus	Valsartan/HCTZ Tablets "OK to Compress"	Withheld – Non-responsive/other products
MYLAN-MDL2875-00669833	Mahanti, Satish	Valsartan-USP-Impurity details.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00669929	Mahanti, Satish	Valsartan product details_V5 dt041114.pptx	Withheld – Non-responsive/other products

Bates Number	Custodian	File Name	Justification for Withholding
MYLAN-MDL2875-00671058	Mahanti, Satish	Valsartan YoY Data.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00671065	Mahanti, Satish	Valsartan dispatches from Jan'13 to till date - All customers - Reg I.XLSX	Withheld – Non-responsive/other products
MYLAN-MDL2875-00671089	Mahanti, Satish	Valsartan Commercial Data 2013 - 2018.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00671170	Mahanti, Satish	Valsartan Commercial Data 2013 - 2018-Batch numbers-US Mkt -Teva.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00671173	Mahanti, Satish	Valsartan Commercial Data 2013 - 2018-Batch numbers-US Mkt -Teva.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00671176	Mahanti, Satish	Valsartan Commercial Data 2013 - 2018-Batch numbers-Sent v1-Other Mkt.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00671367	Mahanti, Satish	Valsartan.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00671401	Mahanti, Satish	Valsartan - official complaint	Withheld – Non-responsive/other products
MYLAN-MDL2875-00671407	Mahanti, Satish	RE: Valsartan_Pliva - Complaint intimation	Withheld – Non-responsive/other products
MYLAN-MDL2875-00671411	Mahanti, Satish	Valsartan_Pliva - Complaint intimation	Withheld – Non-responsive/other products
MYLAN-MDL2875-00671467	Mahanti, Satish	Valsartan_NDMA_NDEA_Polpharma.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00671471	Mahanti, Satish	VALSARTAN ROS.PDF	Withheld – Non-responsive/other products
MYLAN-MDL2875-00671473	Mahanti, Satish	Valsartan_NDMA_NDEA_Polpharma.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00671476	Mahanti, Satish	Valsartan Polpharma Declaration-19 Jul 2018.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00671478	Mahanti, Satish	VALSARTAN ROS- 17 Jul 2018.PDF	Withheld – Non-responsive/other products
MYLAN-MDL2875-00671480	Mahanti, Satish	Valsartan_NDMA_NDEA_Polpharma- 12 Dec 2018 (NDEA values of the API batches tha	Withheld – Non-responsive/other products
MYLAN-MDL2875-00671481	Mahanti, Satish	RE: Valsartan -Polpharma/ order no. 214909	Withheld – Non-responsive/other products
MYLAN-MDL2875-00671483	Mahanti, Satish	Valsartan -Polpharma/ order no. 214909	Withheld – Non-responsive/other products
MYLAN-MDL2875-00671485	Mahanti, Satish	RE: Valsartan -Polpharma/ order no. 217986	Withheld – Non-responsive/other products
MYLAN-MDL2875-00671493	Mahanti, Satish	RE: Valsartan for Polpharma - PSD method for old and new products	Withheld – Non-responsive/other products
MYLAN-MDL2875-00671497	Mahanti, Satish	RE: Valsartan for Polpharma-PSD method for old and new products -(by dry method) - N	Withheld – Non-responsive/other products
MYLAN-MDL2875-00671505	Mahanti, Satish	RE: Valsartan order / PO 255488 - Polpharma	Withheld – Non-responsive/other products
MYLAN-MDL2875-00671586	Mahanti, Satish	Valsartan USP, USDMF#018253-Customer Notification-August 2018	Withheld – Non-responsive/other products
MYLAN-MDL2875-00671697	Mahanti, Satish	Valsartan Nitrosamine results.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00671698	Mahanti, Satish	Valsartan Response 21.08.2018.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00671704	Mahanti, Satish	Valsartan 2016 batches declaration.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00671705	Mahanti, Satish	Valsartan 2017 batches declaration.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00671746	Mahanti, Satish	Valsartan-DMF_18253_LOA_Teva_15062010.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00672227	Mahanti, Satish	valsartan batch numbers.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00672262	Mahanti, Satish	Valsartan_Flowchart_comparison_VLN_to_VST.PDF	Withheld – Non-responsive/other products
MYLAN-MDL2875-00672286	Mahanti, Satish	Valsartan-Response-Eurofarma-21.08.2018.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00672287	Mahanti, Satish	Valsartan-Response-EMS-21.08.2018.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00672318	Mahanti, Satish	Valsartan - Destruction certificate.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00675228	Malki, Reem	RE: Valsartan : test of Api for non-distributed products	Withheld – Non-responsive/other products
MYLAN-MDL2875-00675230	Malki, Reem	Valsartan_NDMA_NDEA content Results_BE.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00675485	Malki, Reem	Valsartan_Recall Summary_by Market_010219.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00675515	Malki, Reem	Valsartan Summary_17January2019.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00676311	Medikonduri, Suresh	Recovered O-xylene spec.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00679126	Muntode, Valentine	Valsartan Material Codes.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00679940	Muntode, Valentine	Valsartan related CAPA.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00680181	Murthy, GNVS	VALSARATAN.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00680498	Murthy, GNVS	Valsartan COA.PDF	Withheld – Non-responsive/other products
MYLAN-MDL2875-00682239	Murthy, GNVS	Valsartan_USP_RMT_00.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00682397	Murthy, GNVS	Valsartan Chemo PL.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00684534	MVRBS, Subrahmanyam	Valsartan Disodium equipment mapping 07.09.17.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00687782	MVRBS, Subrahmanyam	Valsartan Elemental impurities declaration.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00690306	Npatil, Durvas	Valsartan API hygroscopicity.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00692034	Npatil, Durvas	FW: USFDA Notice of Inspection_Mylan Laboratories Limited-FEI # 3008316970	Withheld – Non-responsive/other products
MYLAN-MDL2875-00693367	Npatil, Durvas	Valsartan hCtZ Tablet 160-25 mg.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00694769	Owens, Walter	valsaratan_EMA-Mylan_Response-27072018.doc	Withheld – Non-responsive/other products
MYLAN-MDL2875-00695250	Patel, Chetan	Valsartan tabl USP 320mg_Skeleton (Modified VST process).doc	Withheld – Non-responsive/other products

Bates Number	Custodian	File Name	Justification for Withholding
MYLAN-MDL2875-00695670	Plastina, Michael	Valsartan USP.jpg	Withheld – Non-responsive/other products
MYLAN-MDL2875-00698388	Prerepa, Sreenivasarao	RE: Valsartan products with API manufactured by Mylan	Withheld – Non-responsive/other products
MYLAN-MDL2875-00698402	Prerepa, Sreenivasarao	Valsartan-USDMF- Update details.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00698424	Prerepa, Sreenivasarao	Valsartan-containing products (draft) press release	Withheld – Non-responsive/other products
MYLAN-MDL2875-00698486	Prerepa, Sreenivasarao	Valsartan API Supplies - US Mkt -Teva.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00698750	Prerepa, Sreenivasarao	Valsartan VSD - Lantech Mylan -2018.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00699439	Prerepa, Sreenivasarao	Valsartan Tab (001).xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00699444	Prerepa, Sreenivasarao	Valsartan NDMA, NDEA, NEIA and NDIA Content by GC-MS AMV Protocol.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00699632	Prerepa, Sreenivasarao	Valsartan NDMA OOS investigation report Draft 16102019.docx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00702585	Rawjee, Yasir	Valsartan Summary of ALL Recalls for Legal Jan 17 2019_v3.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00704933	Talton, Wayne	Valsartan extrapolation.xls	Withheld – Non-responsive/other products
MYLAN-MDL2875-00705032	Talton, Wayne	Valsartan_CEP 2009-346_Communication of 12Nov218.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00705033	Talton, Wayne	Valsartan_CEP 2009-396_14Aug2018.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00708144	Tamalampudi, Satyabalaji	RE: Valsartan - suppliers of intermediates	Withheld – Non-responsive/other products
MYLAN-MDL2875-00708146	Tamalampudi, Satyabalaji	Fw: Valsartan Mylan source	Withheld – Non-responsive/other products
MYLAN-MDL2875-00710439	Vaidya, Pradeep	Valsartan - Odor Taste - US.pptx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00712188	Vaidya, Pradeep	Valsartan, Distribution Data Status of batches Jan 07 2019.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00712296	Vaidya, Pradeep	Valsartan, Monthly Status Report 8 Product Return wholesale retail.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00712350	Vaidya, Pradeep	Valsartan, Distribution Data Dec 30 2019.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00712434	Vaidya, Pradeep	Valsartan, Monthly Status Report 10 ConsumerProductReturn.xls	Withheld – Non-responsive/other products
MYLAN-MDL2875-00712435	Vaidya, Pradeep	Valsartan, Monthly Status Report 10 ConsumerProductReturn.xls	Withheld – Non-responsive/other products
MYLAN-MDL2875-00713885	Vasireddy, Srinivas	valsartan costing updated.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00714917	Venkatasagi, Varma	Valsartan Non moving stocks.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00716098	Venkatasagi, Varma	Valsartan Report (Assay by Potentiometry).pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00717534	Venkatasagi, Varma	Valsartan complaint Investigation Report_06.10.2017.doc	Withheld – Non-responsive/other products
MYLAN-MDL2875-00719055	Venkatasagi, Varma	Valsartan SN for Biocon.xlsx	Withheld – Non-responsive/other products
MYLAN-MDL2875-00719461	Venkatasagi, Varma	Valsartan_VAA.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00719463	Venkatasagi, Varma	Valsartan.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00720422	Venkatasagi, Varma	O-Xylene Process flow.doc	Withheld – Non-responsive/other products
MYLAN-MDL2875-00720655	Venkatasagi, Varma	RE: Valsartan /Hydrochlorothiazide Tablets (80 mg/12.5 mg, 160 mg/12.5 mg & 160 mg/20 mg)	Withheld – Non-responsive/other products
MYLAN-MDL2875-00720688	Venkatasagi, Varma	O-Xylene.pdf	Withheld – Non-responsive/other products
MYLAN-MDL2875-00720693	Venkatasagi, Varma	VALSARTAN PROCESS FLOW (VST) INCLUDING O-XYLENE RECOVERY_02.12.18	Withheld – Non-responsive/other products
MYLAN-MDL2875-00720775	Venkatasagi, Varma	Valsartan Agreeemnt.pdf	Withheld – Non-responsive/other products
PRINSTON00086017	Du, Jun	Re: Re: FDA 483 答复	Withheld - Other Product(s)
PRINSTON00086096	Du, Jun	Responses to FDA Observation 2(b)_Response Draft June 7.doc	Withheld - Other Product(s)
PRINSTON00119407	Zhu, Lesley	Valsartan recall case log.xlsx	Withheld - Other Product(s)
PRINSTON00148756	Wang, Minfa	Nitrosamines1.pdf.accreport.html	Withheld - Other Product(s)
PRINSTON00315491	Wang, Minfa	Responses for Internal Audit Report for the year 2019	Withheld - Other Product(s)
PRINSTON00341435	Wang, Minfa	RE: RE: FDA PAI Planing Weekly meeting	Withheld - Other Product(s)
PRINSTON00344351	Gergis, Remonda	Re: Re: Harvard/Major Supplier Questionnaire	Withheld - Other Product(s)
PRINSTON00345061	Gergis, Remonda	Re: Re: Huahai Xunqiao site FDA OAI	Withheld - Other Product(s)
TEVA-MDL2875-00039181	Fluch, Joerg	Valsartan 31-12-2018 - Q4_21-1-2019 (update GF).xlsx	Withheld - Other Product(s)
TEVA-MDL2875-00052119	Nassall, Jens	Valsartan JP 16-1 monograph.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00073583	Barreto, Dan	Sartan Bracket Testing Strategy DRAFT 09NOV20.docx	Withheld - Other Product(s)
TEVA-MDL2875-00073901	Barreto, Dan	SARTAN API NDMAand other Nitosoamine Impurity (2).docx	Withheld - Other Product(s)
TEVA-MDL2875-00074834	Barreto, Dan	Nitrosamines Steering Committee 13Dec19.doc	Withheld - Other Product(s)
TEVA-MDL2875-00082780	Fluch, Joerg	RE: Valsartan return to Huahai - Instructions	Withheld - Other Product(s)
TEVA-MDL2875-00084395	Lyons, Claire	Valsartan Declaration.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00086520	Lyons, Claire	FW: Valsartan - updated risk assessment	Withheld - Other Product(s)
TEVA-MDL2875-00086855	Lyons, Claire	Valsartan NDMA NDEA - All other.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00091188	Nassall, Jens	RE: Valsartan 2019 standard price - Summary	Withheld - Other Product(s)

Bates Number	Custodian	File Name	Justification for Withholding
TEVA-MDL2875-00096782	Barreto, Dan	Valsartan Declaration - EMA 26-08-18.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00097005	Barreto, Dan	Valsartan - Impurity batches for Aurobindo	Withheld - Other Product(s)
TEVA-MDL2875-00097181	Barreto, Dan	RE: Standards for NDMA/ NDEA/ Other impurities	Withheld - Other Product(s)
TEVA-MDL2875-00097326	Barreto, Dan	RE: Sartan assessments	Withheld - Other Product(s)
TEVA-MDL2875-00099046	Barreto, Dan	Nitrosamines Update -Jan 13 2020.pptx	Withheld - Other Product(s)
TEVA-MDL2875-00101250	Fluch, Joerg	Valsartan return to Huahai - Instructions	Withheld - Other Product(s)
TEVA-MDL2875-00103960	Lyons, Claire	RE: Sartan API number of batches	Withheld - Other Product(s)
TEVA-MDL2875-00104154	Lyons, Claire	Sartans Swissmedic publication	Withheld - Other Product(s)
TEVA-MDL2875-00104405	Lyons, Claire	Valsartan EMA referral Dupnitsa.xlsx	Withheld - Other Product(s)
TEVA-MDL2875-00104480	Lyons, Claire	RE: Sartan API - Request for Information	Withheld - Other Product(s)
TEVA-MDL2875-00104723	Lyons, Claire	Nitrosoamine impurities in IRBESARTAN VR.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00104724	Lyons, Claire	Nitrosoamine impurities in Losartan Potassium report.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00104999	Lyons, Claire	Nitrosoamine impurities in Losartan Potassium report.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00105992	Lyons, Claire	RE: Sartan APO Information	Withheld - Other Product(s)
TEVA-MDL2875-00106167	Lyons, Claire	VALSARTAN 1.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00109965	Nassall, Jens	RE: Valsartan return to Huahai - Instructions	Withheld - Other Product(s)
TEVA-MDL2875-00110433	Nassall, Jens	RE: Valsartan - CEP Huahai - potential timeline	Withheld - Other Product(s)
TEVA-MDL2875-00112834	Sawyer, Corey	Sartan_17.10.2018.xlsx	Withheld - Other Product(s)
TEVA-MDL2875-00113864	Sawyer, Corey	RE: Valsartan API support testing for NDMA and NDEA	Withheld - Other Product(s)
TEVA-MDL2875-00118327	Barreto, Dan	Valsartan - Formulation_Halfar_Dupnitsa_Goa_31.10.2018.xlsx	Withheld - Other Product(s)
TEVA-MDL2875-00121193	Fluch, Joerg	NITROSAMINES ANALYTICAL METHOD VALIDATION SUMMARY REPORT METFOR	Withheld - Other Product(s)
TEVA-MDL2875-00121476	Karlsson, Stefan	Risk evaluation for launches - 2019-2022.xlsx	Withheld - Other Product(s)
TEVA-MDL2875-00121577	Lyons, Claire	Valsartan-Teva India.xlsx	Withheld - Other Product(s)
TEVA-MDL2875-00127071	Sawyer, Corey	RE: Sartan Information	Withheld - Other Product(s)
TEVA-MDL2875-00129310	Truemper, Constance	Valsartan HCTZ_FAR (MAL)_Follow Up 09 JUL 2018 e-copy.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00129311	Truemper, Constance	Valsartan_FAR (MAL)_Follow Up 09 JUL 2018 e-copy.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00130145	Binsol, Tony	Valsartan 320mg Lot 1263943A - verification of Hold Status 01 MAY 2019.docx	Withheld - Other Product(s)
TEVA-MDL2875-00130965	Clark, Napoleon	Valsartan MPS.xlsx	Withheld - Other Product(s)
TEVA-MDL2875-00133628	Delgaudio, Joyce	Valsartan Launch Plan 7 31 2014 v2.xlsx	Withheld - Other Product(s)
TEVA-MDL2875-00133747	Delgaudio, Joyce	Valsartan HCTZ - 958966A_COC.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00133749	Delgaudio, Joyce	Valsartan - 961646A_COC.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00133752	Delgaudio, Joyce	Valsartan HCTZ - 958968A_COC.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00134364	Delicato, Tony	Valsartan HCTZ 160mg-12.5mg Tablet Initial FAR Form 24_MAR_2015.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00135690	Fluch, Joerg	Valsartan-VST Vs VAA-comparison.doc	Withheld - Other Product(s)
TEVA-MDL2875-00136028	Fluch, Joerg	Valsartan_Huahai_5000786_Incoterms pricing.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00137214	Fluch, Joerg	Valsartan API particle size	Withheld - Other Product(s)
TEVA-MDL2875-00138177	Fluch, Joerg	Valsartan 2015.xlsx	Withheld - Other Product(s)
TEVA-MDL2875-00138315	Fluch, Joerg	Valsartan_CEP & Annex_04.08.2016.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00139035	Fluch, Joerg	Valsartan zaliha 03122018.xlsx	Withheld - Other Product(s)
TEVA-MDL2875-00139261	Fluch, Joerg	Valsartan - more test results needed.xlsx	Withheld - Other Product(s)
TEVA-MDL2875-00139607	Fluch, Joerg	Valsartan_offers_comparison.xlsx	Withheld - Other Product(s)
TEVA-MDL2875-00140088	Fluch, Joerg	Valsartan COA (EP) 67819020614-15-16.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00140418	Fluch, Joerg	Valsartan - Huahai.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00140989	Fluch, Joerg	Valsartan ASMF Applicant Part Ver# 001 PLIVA Croatia Ltd. 28.11.2018.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00140994	Fluch, Joerg	Valsartan brief description of process.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00141673	Fluch, Joerg	Valsartan Assessment report.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00145974	Galownia, Kevin	Valsartan Tablets SDS.PDF	Withheld - Other Product(s)
TEVA-MDL2875-00146633	Gatt, Elton	Valsartan Hct 160 25mg 2005793 S63613 Dissolution Profile.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00146983	Gatt, Elton	Valsartan B8086 0.1M HCl 1-6, 7-12.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00147278	Gatt, Elton	Valsartan-Hct 320-12.5mg 2005798 S83271 Assay.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00148178	Gatt, Elton	Valsartan API batches.xlsx	Withheld - Other Product(s)

Bates Number	Custodian	File Name	Justification for Withholding
TEVA-MDL2875-00148942	Gatt, Elton	RE: Valsartan Spirig HC / API Zhejiang Huahai / GMP non-compliance-statement	Withheld - Other Product(s)
TEVA-MDL2875-00150592	Gray, Elisabeth	FW: Valsartan API - DMF updates	Withheld - Other Product(s)
TEVA-MDL2875-00150607	Gray, Elisabeth	Valsartan_TP_20170330.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00151074	Gray, Elisabeth	Valsartan HCT USA_Draft_Stability Protocol 20.10.2017-JD-SD_Dupnitsa com....docx	Withheld - Other Product(s)
TEVA-MDL2875-00151079	Gray, Elisabeth	Valsartan HCT USA_Draft_Stability Protocol 20.10.2017-JD-SD.DOCX	Withheld - Other Product(s)
TEVA-MDL2875-00151878	Gray, Elisabeth	RE: Valsartan / Valsartan/HCTZ	Withheld - Other Product(s)
TEVA-MDL2875-00152317	Gray, Elisabeth	Valsartan +HCT FU Apr 11 2018 meeting minutes.doc	Withheld - Other Product(s)
TEVA-MDL2875-00156202	Koleto, Christina	Valsartan HCTZ one time buy 20140224.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00157525	McBryan, Danny	Valsartan_ update on review.docx	Withheld - Other Product(s)
TEVA-MDL2875-00159820	Pastore, Jill	Valsartan and HCTZ Tabs.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00160889	Pavlov, Kiril	Valsartan HTC 160_25mg 017211 25_60_48m BL VER2.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00161191	Pavlov, Kiril	Valsartan CEP Information Copy.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00162535	Pavlov, Kiril	Valsartans.pptx	Withheld - Other Product(s)
TEVA-MDL2875-00162976	Pavlov, Kiril	Valsartan Quality declaration.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00163106	Pavlov, Kiril	Nitrosamines_Questionnaire_2019-11-18_Actavis.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00163132	Pavlov, Kiril	nitrosamines-emea-h-a53-1490-questions-answers-information-nitrosamines-....pdf	Withheld - Other Product(s)
TEVA-MDL2875-00163185	Pavlov, Kiril	EMA sartan-medicines-companies-review-manuf-processes-01feb19.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00165756	Segura, Jose Luis	Valsartan_Zhejiang Huahai GMP non-compliance.docx	Withheld - Other Product(s)
TEVA-MDL2875-00166267	Segura, Jose Luis	Valsartan - Volume availability for 2020 by Market-SKU.XLSX	Withheld - Other Product(s)
TEVA-MDL2875-00166855	Sualhi, Rana	Valsartan_Reddy_Lab_Request_060911.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00166864	Sualhi, Rana	Valsartan_Reddy_Lab_Request_060911.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00166966	Sualhi, Rana	VALSARTAN AZID	Withheld - Other Product(s)
TEVA-MDL2875-00167019	Sualhi, Rana	valsartan.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00167752	Sualhi, Rana	Valsartan (IL_JLM) representative CoA for US, Jerusalem site in Israel.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00167799	Sualhi, Rana	Valsartan_VST_Acc .pdf	Withheld - Other Product(s)
TEVA-MDL2875-00168771	Tomsky, Scott	Valsartan FAR products list.xls	Withheld - Other Product(s)
TEVA-MDL2875-00168777	Tomsky, Scott	Valsartan FAR products list.xlsx.xls	Withheld - Other Product(s)
TEVA-MDL2875-00171322	Binsol, Tony	RE: Sartans - Temporary interim limits for NMBA, DIPNA and EIPNA impurities	Withheld - Other Product(s)
TEVA-MDL2875-00175037	Clark, Napoleon	Red Carpet for Product Operations_01 03 2017.pptx	Withheld - Other Product(s)
TEVA-MDL2875-00183847	De Vito, Joseph	Valsartan Timeline 10-23-12.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00187229	De Vito, Joseph	Valsartan Risk Assessment GNTM- G2014-353.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00190055	De Vito, Joseph	Nitrosamines1.pdf.accreport.html	Withheld - Other Product(s)
TEVA-MDL2875-00190554	Delgaudio, Joyce	Valsartan initial stocking 111512.xlsx	Withheld - Other Product(s)
TEVA-MDL2875-00195709	Delgaudio, Joyce	Nitrosamines in Pharmaceuticals_Canada.pptx	Withheld - Other Product(s)
TEVA-MDL2875-00198473	Delicato, Tony	Risk Assessment-PAL.docx	Withheld - Other Product(s)
TEVA-MDL2875-00208366	Fluch, Joerg	RE: Valsartan EP ex Jubilant/ 2016 price for the pharma and potential R&D project with T	Withheld - Other Product(s)
TEVA-MDL2875-00210536	Fluch, Joerg	RE: Valsartan/Divi's - demand 2019	Withheld - Other Product(s)
TEVA-MDL2875-00215020	Galownia, Kevin	Valsartan Tablets_PPA HDMA.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00220161	Galownia, Kevin	RE: Valsartan	Withheld - Other Product(s)
TEVA-MDL2875-00233474	Gatt, Elton	Valsartan EMA Referral.xlsx	Withheld - Other Product(s)
TEVA-MDL2875-00242908	Gray, Elisabeth	Valsartan +HCT FU May 23 2018 meeting minutes.doc	Withheld - Other Product(s)
TEVA-MDL2875-00244367	Hatt, David	Valsartan Impurity D CofA.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00255894	Korcia, Avi	VALSARTAN_Flow Chart.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00255896	Korcia, Avi	Valsartan_MSDS_201504.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00256559	Lyons, Claire	RE: VERY URGENT - NUMBER OF RECALLED BATCHES - VALSARTAN	Withheld - Other Product(s)
TEVA-MDL2875-00257662	Nassall, Jens	Valsartan prism.xls	Withheld - Other Product(s)
TEVA-MDL2875-00259845	Nudelman, Raphael	Sartan ROS.doc	Withheld - Other Product(s)
TEVA-MDL2875-00268048	Pastore, Jill	Valsartan_Quality equivalence data.PDF	Withheld - Other Product(s)
TEVA-MDL2875-00268098	Pastore, Jill	VALSARTAN USP Teva Tech.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00268102	Pastore, Jill	Valsartan- TAPI-Cover letter Answer Sep2011.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00268358	Pastore, Jill	Valsartan XRD Evaluation Report 0711.pdf	Withheld - Other Product(s)

Bates Number	Custodian	File Name	Justification for Withholding
TEVA-MDL2875-00274694	Pavlov, Kiril	Valsartan-Teva India-updated 20180727.xlsx	Withheld - Other Product(s)
TEVA-MDL2875-00277094	Pavlov, Kiril	ema-advises-companies-steps-take-avoid-nitrosamines-human-medicines_en.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00277102	Pavlov, Kiril	Valsartan Swissmedic cover letter.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00280418	Schwartz, Orit	Valsartan_Testing_July12.pptx	Withheld - Other Product(s)
TEVA-MDL2875-00280493	Schwartz, Orit	RE: Valsartan drug product formula	Withheld - Other Product(s)
TEVA-MDL2875-00280849	Schwartz, Orit	Valsartan_Analytical Method_Timelines.pptx	Withheld - Other Product(s)
TEVA-MDL2875-00282890	Schwartz, Orit	RE: Sartans Routine Testing Strategy_3 Dec 2018.pptx	Withheld - Other Product(s)
TEVA-MDL2875-00287990	Segura, Jose Luis	Valsartan status	Withheld - Other Product(s)
TEVA-MDL2875-00289119	Segura, Jose Luis	Valsartan_OLT update v3.pptx	Withheld - Other Product(s)
TEVA-MDL2875-00290906	Segura, Jose Luis	Valsartan Update.pptx	Withheld - Other Product(s)
TEVA-MDL2875-00314184	Sualhi, Rana	FW: Valsartan	Withheld - Other Product(s)
TEVA-MDL2875-00316643	Tomsky, Scott	Valsartan Art 31 - CHMP rapporteurs 2nd preliminary joint assessment on risk_to MAHs.	Withheld - Other Product(s)
TEVA-MDL2875-00316644	Tomsky, Scott	Valsartan Art 31 - CHMP rapporteurs preliminary joint assessment on risk_toMAHs.docx	Withheld - Other Product(s)
TEVA-MDL2875-00318489	Vadsola, Narendra	Valsarta ROS_Triethylamine.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00318490	Vadsola, Narendra	Valsartan ROS_ZnCl2.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00323856	Barreto, Dan	Valsartan Art 31 - Letter of representation.doc	Withheld - Other Product(s)
TEVA-MDL2875-00323962	Barreto, Dan	Valsartan Article 31 referral - Notification.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00324408	Barreto, Dan	Valsartan Article 31 referral - Annex I.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00324731	Barreto, Dan	Sartans Synthesis NDEA contamination_Communication.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00324733	Barreto, Dan	EMA Update on medicines containing valsartan_NDEA_13sep18.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00324994	Barreto, Dan	EMA review of impurities in sartan medicines 21sep19.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00324996	Barreto, Dan	EMA Update Review extended to other sartans 21sep18.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00326008	Barreto, Dan	Valsartan EMA Referral - Zagreb.xlsx	Withheld - Other Product(s)
TEVA-MDL2875-00326093	Barreto, Dan	Valsartan Mylan list of SKUs/ Markets	Withheld - Other Product(s)
TEVA-MDL2875-00328321	Barreto, Dan	Valsartan_FG_Stocks_07.10.2019.xlsx	Withheld - Other Product(s)
TEVA-MDL2875-00329160	Binsol, Tony	VALSARTAN AZIDE-DECLARATION FOR NIEA AND NDIA-23.03.2019.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00329254	Binsol, Tony	Nitroso Status_06.04.2019.xlsx	Withheld - Other Product(s)
TEVA-MDL2875-00350834	De Vito, Joseph	Valsartan Update Meeting	Withheld - Other Product(s)
TEVA-MDL2875-00367791	Fluch, Joerg	Risk management.docx	Withheld - Other Product(s)
TEVA-MDL2875-00368778	Fluch, Joerg	Valsartan CAC - Functional Update_Areas of Focus_Template.pptx	Withheld - Other Product(s)
TEVA-MDL2875-00369261	Fluch, Joerg	Valsartan CEP suspension notification_16Nov2018.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00370219	Fluch, Joerg	Valsartan - Settlement Agreement - Zydus 15 05 2019.docx	Withheld - Other Product(s)
TEVA-MDL2875-00370223	Fluch, Joerg	Valsartan_RI-CEP 2009-396-Rev 04_May 24 2019_Reference Copy.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00370410	Fluch, Joerg	valsartan, Irbesartan - PO/receipt data	Withheld - Other Product(s)
TEVA-MDL2875-00389826	Gatt, Elton	Valsartan HCT.xlsx	Withheld - Other Product(s)
TEVA-MDL2875-00389827	Gatt, Elton	Valsartan tbl.xlsx	Withheld - Other Product(s)
TEVA-MDL2875-00392067	Gatt, Elton	Valsartan_12 July 2018.pptx	Withheld - Other Product(s)
TEVA-MDL2875-00392319	Gatt, Elton	RE: Sartan APIs request from Health Canada	Withheld - Other Product(s)
TEVA-MDL2875-00395110	Gray, Elisabeth	Valsartan Request 2.12.18.xlsx	Withheld - Other Product(s)
TEVA-MDL2875-00395165	Gray, Elisabeth	Valsartan +HCT FU May 9 2018 meeting minutes.doc	Withheld - Other Product(s)
TEVA-MDL2875-00395484	Gray, Elisabeth	Sartan-Response-TEVA.PDF	Withheld - Other Product(s)
TEVA-MDL2875-00396010	Gray, Elisabeth	RE: Sartan Responses	Withheld - Other Product(s)
TEVA-MDL2875-00397150	Gray, Elisabeth	Valsartan_Other Sartan Product CAC- EM Sponsor Update_16 AUG_2019_PS.PPTX	Withheld - Other Product(s)
TEVA-MDL2875-00407176	Lyons, Claire	Valsartan Article 31 referral - CHMP list of questions to be addressed b....pdf	Withheld - Other Product(s)
TEVA-MDL2875-00407854	Lyons, Claire	Valsartan API_UPDATED_6-29-18.docx	Withheld - Other Product(s)
TEVA-MDL2875-00408220	Lyons, Claire	Valsartan CAC - Functional Update_Areas of Focus_Template.pptx	Withheld - Other Product(s)
TEVA-MDL2875-00408427	Lyons, Claire	EMA Update Review extended to other sartans 21sep18.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00408862	Lyons, Claire	RE: Valsartan - suppliers of intermediates	Withheld - Other Product(s)
TEVA-MDL2875-00411258	Lyons, Claire	Sartans Testing implementation - Answer to Authoriteis	Withheld - Other Product(s)
TEVA-MDL2875-00411321	Lyons, Claire	Valsartan investigation report redacted copy 26nov'18.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00411330	Lyons, Claire	Sartans Testing implementation - Answer to Authoriteis	Withheld - Other Product(s)

Bates Number	Custodian	File Name	Justification for Withholding
TEVA-MDL2875-00411424	Lyons, Claire	RE: Valsartan mono/combo - OP FILE - ASAP	Withheld - Other Product(s)
TEVA-MDL2875-00411425	Lyons, Claire	Valsartan_HK_TCI_Opava_response to DL.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00413893	Lyons, Claire	RE: Telmisartan NDMA/NDEA	Withheld - Other Product(s)
TEVA-MDL2875-00413932	Lyons, Claire	RE: Sartans	Withheld - Other Product(s)
TEVA-MDL2875-00414476	Lyons, Claire	Valsartan Ph.Eur-COAs.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00414478	Lyons, Claire	Valsartan CEP suspension notification_16Nov2018.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00414481	Lyons, Claire	valsartan_NDEA Evaluation-28112018.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00414482	Lyons, Claire	Valsartan_communication to customers_Nov2018.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00415546	Lyons, Claire	Valsartan analytical method and method validation data for nitrosoimpuri....pdf	Withheld - Other Product(s)
TEVA-MDL2875-00416669	McBryan, Danny	FW: Valsartan-containing products - Article 31 Referral response	Withheld - Other Product(s)
TEVA-MDL2875-00416773	McBryan, Danny	RE: Valsartan in Russia: status update	Withheld - Other Product(s)
TEVA-MDL2875-00424689	Nassall, Jens	Valsartan other cost penalty payments summary file Q3-19.xlsx	Withheld - Other Product(s)
TEVA-MDL2875-00424753	Nassall, Jens	Valsartan_cashout_20190823.xlsm	Withheld - Other Product(s)
TEVA-MDL2875-00424755	Nassall, Jens	Valsartan_Medis ehf credit invoices to customers 31.08.2019.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00424764	Nassall, Jens	FW: Valsartan Huahai + Mylan - >>> updates 31/3/2019	Withheld - Other Product(s)
TEVA-MDL2875-00430890	Pastore, Jill	Valsartan - customers notification- Azid process Jan2010.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00431547	Pastore, Jill	Valsartan Azide Demo COA.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00437873	Pavlov, Kiril	Valsartan DMF version-.xlsx	Withheld - Other Product(s)
TEVA-MDL2875-00437877	Pavlov, Kiril	Valsartan recall report Malta.htm	Withheld - Other Product(s)
TEVA-MDL2875-00438001	Pavlov, Kiril	RE: Sartans - Temporary interim limits for NMBA, DIPNA and EIPNA impurities	Withheld - Other Product(s)
TEVA-MDL2875-00438331	Pavlov, Kiril	Valsartan Micra specifications.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00438417	Pavlov, Kiril	Vals_HCT_Testing results_Screening.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00438563	Pavlov, Kiril	nitrosamines-emea-h-a53-1490-questions-answers-information-nitrosamines-marketing-a	Withheld - Other Product(s)
TEVA-MDL2875-00440721	Sawyer, Corey	Valsartan API_Statement -FINAL_6-28-18.docx	Withheld - Other Product(s)
TEVA-MDL2875-00441688	Sawyer, Corey	Valsartan API Batches NDMA analysis for Switzerland	Withheld - Other Product(s)
TEVA-MDL2875-00441709	Sawyer, Corey	VALSARTAN_ZHEJIANG HUAHAI PHARM.CO LT 01D_C5355-15-069	Withheld - Other Product(s)
TEVA-MDL2875-00441718	Sawyer, Corey	VALSARTAN TIN FREE ZHEJIANG HUAHAI China 01D_C5523 -17- 539 2538 - 24	Withheld - Other Product(s)
TEVA-MDL2875-00441735	Sawyer, Corey	VALSARTAN ZHEJIANG HUAHAI PHARM.CO LT 01D_C5523_15_135 2	Withheld - Other Product(s)
TEVA-MDL2875-00441737	Sawyer, Corey	VALSARTAN, ZHEJIANG HUAHAI PHARM.China, 01D_C5355-15-240 153-28.03.20	Withheld - Other Product(s)
TEVA-MDL2875-00441742	Sawyer, Corey	VALSARTAN, ZHEJIANG HUAHAI PHARM.China, 01D_C5523-16-052 0968-06.06.20	Withheld - Other Product(s)
TEVA-MDL2875-00441836	Sawyer, Corey	Risk from NDMA remains low, a related substance NDEA also being investigated.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00442166	Sawyer, Corey	Valsartan Media and Scientific Surveillance.pptx	Withheld - Other Product(s)
TEVA-MDL2875-00443291	Sawyer, Corey	Risk Assessment_Valsartan_NDMA_NDEA.PDF	Withheld - Other Product(s)
TEVA-MDL2875-00443395	Sawyer, Corey	Valsartan rtp Mylan batch list AT.xlsx	Withheld - Other Product(s)
TEVA-MDL2875-00444762	Sawyer, Corey	RE: Telmisartan Testing Requirements - Malta Impact	Withheld - Other Product(s)
TEVA-MDL2875-00445110	Sawyer, Corey	Valsartan- Zhejiang Huahai blocked batches packaged at HBM.xlsx	Withheld - Other Product(s)
TEVA-MDL2875-00445114	Sawyer, Corey	VALSARTAN-RTP C. 160/25 FT Lifting of block batch U27653R	Withheld - Other Product(s)
TEVA-MDL2875-00445115	Sawyer, Corey	VALSARTAN/ HCT160/25MG FT U27653 + Bulk 1180455 API VLS1802044 + VLS180	Withheld - Other Product(s)
TEVA-MDL2875-00445130	Sawyer, Corey	Valsartan - Lifting of block batches with API from Jubilant 561/18,VRS,	Withheld - Other Product(s)
TEVA-MDL2875-00445131	Sawyer, Corey	RE: Valsartan API Jubilant intermediate Huahai_Meeting minutes TC 22. Nov.	Withheld - Other Product(s)
TEVA-MDL2875-00445135	Sawyer, Corey	RE: Valsartan API Jubilant intermediate Huahai_Meeting minutes TC 22. Nov.	Withheld - Other Product(s)
TEVA-MDL2875-00446818	Sawyer, Corey	Valsartan HCTZ - 864923A.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00446982	Sawyer, Corey	Nitrosamines impurities CAC- EM Sponsor Update 08 JUN 2020.pptx	Withheld - Other Product(s)
TEVA-MDL2875-00449495	Schwartz, Orit	RE: Sartans routine testing - weekly F/U	Withheld - Other Product(s)
TEVA-MDL2875-00457759	Segura, Jose Luis	Valsartan impact on EU markets	Withheld - Other Product(s)
TEVA-MDL2875-00458364	Segura, Jose Luis	Valsartan Status 180712 v2.pptx	Withheld - Other Product(s)
TEVA-MDL2875-00458556	Segura, Jose Luis	Valsartan Art 31 - Start of procedure - letter to MAHs.doc	Withheld - Other Product(s)
TEVA-MDL2875-00458563	Segura, Jose Luis	Valsartan Article 31 referral - Notification.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00458568	Segura, Jose Luis	Valsartan Article 31 referral - Timetable for the procedure.pdf	Withheld - Other Product(s)
TEVA-MDL2875-00461504	Segura, Jose Luis	Valsartan - MYLAN 31-12-2018 - Q4_11-2-2019_FINAL02.xlsx	Withheld - Other Product(s)
TEVA-MDL2875-00461505	Segura, Jose Luis	Valsartan - HUAHAI 31-12-2018 - Q4_18-2-2019_FINAL02.xlsx	Withheld - Other Product(s)

Bates Number	Custodian	File Name	Justification for Withholding
TEVA-MDL2875-00480948	Truemper, Constance	Valsartan Consumer Call Script 7.17_.docx	Withheld - Other Product(s)
ZHP00087944	Wang, Lijie	valsartan job plan-2020.1.20 update.xlsx	Withheld - Other Products
ZHP00111547	Gergis, Remonda	Valsartan 160mg Customers 12-7-2017.xlsx	Withheld - Other Products
ZHP01865900	GE_Jucai	N-Nitrosodimethylamine in Drinking Water_Report 2.pdf	Withheld - Other Product(s)
ZHP01868097	HU_Yuelin	N-Nitrosodimethylamine in Drinking-water.pdf	Withheld - Other Product(s)
ZHP01954008	CHENG_Wei	Risk of contamination by nitrosamine - ZH Duqiao_20181210.docx	Withheld - Other Product(s)
ZHP01975420	CHENG_Wei	sartans-declaration-control-strategy-template ESH0607-huahai.docx	Withheld - Other Product(s)
ZHP02022236	XU_Mi	Recycled solvents questionnaire (supplier).docx	Withheld - Other Product(s)
ZHP02072261	XU_Mi	Valsartan Krka-Huahai 2017	Withheld - Other Product(s)
ZHP02081822	ZHONG_Sheng	nitrosamines-emea-h-a53-1490-questions-answers-information-nitrosamines-....pdf	Withheld - Other Product(s)
ZHP02127925	WANG_Dongqin	Recycled solvents questionnaire (supplier)-Irbesartan.docx	Withheld - Other Product(s)
ZHP02325942	ZHANG_Minli	Risk of contamination by nitrosamine - ZH Duqiao_ Telmisartan.pdf	Withheld - Other Product(s)
ZHP02420733	LIN_Lihong	Responses to FDA Audit Nov 14-18 (2016)-Final.pdf	Withheld - Other Product(s)
ZHP02464785	CHENG_Wei	Responses to FDA Audit.pdf	Withheld - Other Product(s)

## Exhibit D

## Layne Hilton

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**From:** Layne Hilton  
**Sent:** Wednesday, December 02, 2020 4:39 PM  
**To:** CCT@pietragallo.com  
**Cc:** JMR@pietragallo.com; 'Frank H. Stoy'; Valsartan PEC; JPriselac@duanemorris.com; Conlee Whiteley; Adam Slater; Daniel Nigh; David J. Stanoch; rubhon@gmail.com; Behram Parekh  
**Subject:** In re Valsartan - Improperly Withheld Documents

Clem –

I write regarding Mylan's document production

As of my review, Mylan has withheld a staggering 45,036 documents from production on the basis of "other drug/non-responsive." These 45,036 documents are out of 163,597 total documents produced to date. More troubling than this, many of these documents appear to be **highly relevant to the core issues in this case**.

To demonstrate the fallacy of Mylan's relevancy determinations, Plaintiffs have identified just a mere sampling of the documents (including the document's file name taken from the metadata) which Mylan deemed "non-responsive" and consequently withheld from production:

### ***Documents regarding NDMA and NDEA:***

- MYLAN-MDL2875-00573802 (withheld document titled NDMA & NDEA Study Protocol)
- MYLAN-MDL2875-00573800 (withheld document titled NDMA & NDEA Study Report)
- MYLAN-MDL2875-00573801 (withheld document titled NDMA & NDEA Study Analytical Reports)
- MYLAN-MDL2875-00358255 (withheld document titled NDMA & NDEA Study Report – Addendum)
- MYLAN-MDL2875-00301339 (withheld document titled NDMA and NDEA content in Valsartan\_AMT Protocol.docx)
- MYLAN-MDL2875-00368316 (withheld document titled document titled NDMA Declaration.pdf)
- MYLAN-MDL2875-00368315 (withheld document titled NDEA Declaration.pdf)
- MYLAN-MDL2875-00275069 (withheld document titled NDEA, NDIA, NDMA Characterisation reports)
- MYLAN-MDL2875-00507589 (withheld document titled NDEA Impurity.pdf)
- MYLAN-MDL2875-00368106 (withheld document titled ndea\_and\_ndma\_detection\_in\_sartan\_containing\_tablets\_by\_lc-ms-ms.pdf)
- MYLAN-MDL2875-00344253 (withheld document titled NDMA, NDEA, NEIA and NDIA Content by GC-MS AMV Report.pdf)
- MYLAN-MDL2875-00303186 (withheld document titled Nitrosamine Assessment Reports Summary Across MLL API Network\_Final Copy (003).docx)
- MYLAN-MDL2875-00472554 (withheld document titled Nitrosamine Risk Assessment\_Valsartan Tablets.docx)
- MYLAN-MDL2875-00447843 (withheld document titled Nitroso impurities-current status -16042019.xlsx)

### ***Documents regarding the EMA's investigation into the Valsartan Nitrosamine Contamination:***

- MYLAN-MDL2875-00471611 (withheld document titled Sartans Art 31 – CHMP opinion.doc)
- MYLAN-MDL2875-00507121 (withheld document titled Sartans Art 41 – CHMP timetable.doc)
- MYLAN-MDL2875-00311562 (withheld document titled sartans-article-31-referral-chmp-list-questions-be-addressed-api-manufacturers-valsartan-containing\_en.pdf\_)
- MYLAN-MDL2875-00471276 (withheld document titled Sartans Art 31 – Appendix 2 to CHMP opinion – CHMP AR.docx)

***Documents regarding the Valsartan API manufacturing process:***

- MYLAN-MDL2875-00268231 (withheld document titled VLN-2 BBS-B.doc)
- MYLAN-MDL2875-00268229 (withheld document titled VLN-2 B PB-10.doc)
- MYLAN-MDL2875-00268232 (withheld document titled VLN-2BBS—A.doc)
- MYLAN-MDL2875-00268252 (withheld document titled VST Validation costing.pdf)
- MYLAN-MDL2875-00463841 (withheld document titled VST-1-INP.doc)

***Documents regarding the recovered solvents used in the manufacture of Valsartan which resulted in the production of NDEA and the vendors who supply Mylan with recovered solvents:***

- MYLAN-MDL2875-00301437-38 (email regarding “queries from FDA” which attaches a document describing the risks of NDEA formation in recovered o-xylene, and attaches 7 exemplar chromatograms (all withheld) for the recovered o-xylene).
- MYLAN-MDL2875-00431839 (withheld document titled O-Xylene GC Chromatograms [sic])
- MYLAN-MDL2875-00523823 (withheld document titled O-Xylene Recover (VST)-Unit-8.pdf)
- MYLAN-MDL2875-00468154 (withheld document titled O-Xylene VST-VLS-II.pdf)
- MYLAN-MDL2875-00521922 (withheld document titled Valsartan – Lantech.pdf)
- MYLAN-MDL2875-00565036 (withheld document titled Lantech Valsartan status.xls[sic])
- MYLAN-MDL2875-00396840 (withheld document titled Lantech VLN & VST 2.pdf)
- MYLAN-MDL2875-00562623 (withheld document titled Lantech 2011-2019.xls)
- MYLAN-MDL2875-00530121 (withheld document titled Lantech Notification.pdf)
- MYLAN-MDL2875-00396866 (withheld document titled Lantech.Valsartan (VLN) II from Crude Valsartan (VLN) II RE.Rev.03.pdf)

***Documents regarding testing and/or data issues specific to Valsartan and/or recovered solvents used in Valsartan***

- MYLAN-MDL2875-00471146 (withheld document titled Valsartan API Data nashik recovered solvents.xlsx)
- MYLAN-MDL2875-00507240 (withheld document titled Valsartan API batches – requested by customers to check NDEA – revised)
- MYLAN-MDL2875-00531238 (withheld document titled Valsartan Data.xls)
- MYLAN-MDL2875-00383783 (withheld document titled Valsartan impurities.pdf[sic])
- MYLAN-MDL2875-00270210 (withheld document titled valsartan initial chromatography part 2 of 2.pdf[sic])
- MYLAN-MDL2875-00509570 (withheld document titled NOTIFICATION OOS\_Valsartan HCTZ 2015.pdf)

***Documents regarding the facilities where Valsartan was manufactured:***

- MYLAN-MDL2875-00403234 (withheld document titled U-3 March Monthly Report 2011.doc)
- MYLAN-MDL2875-00558287 (withheld document titled Unit-3\_MIS report-June 11.xls)
- MYLAN-MDL2875-00506150 (withheld document titled USFDA EIR Report\_2014 which appears to be about Unit III)
- MYLAN-MDL2875-00570994 (withheld document titled USFDA\_EIR\_2018.pdf which appears to be about Unit 8)
- MYLAN-MDL2875-00466782 (withheld document titled Unit-8.docx)

The above-list is merely demonstrative and in no way meant to be exhaustive of all improperly withheld documents. Given the sheer volume of the universe of withheld documents (essentially 1 out of every 4 documents produced), Plaintiffs cannot (and should not) be required to go through and challenge each and every one of the 45,036 documents.

As such, Plaintiffs ask Mylan to re-produce all 45,036 documents withheld as “non-responsive” in full, and to do so immediately.

Plaintiffs are available to meet and confer with Mylan prior to next week’s Case Management Conference, such that the Parties can raise any outstanding issues regarding Mylan’s improper relevance review with the Court.

Best,

Layne

Layne Hilton  
Kanner & Whiteley, L.L.C.  
701 Camp Street  
New Orleans, LA 70130  
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ALL COPIES OF THE ORIGINAL MESSAGE. \_\_\_\_\_

## Exhibit E

## Layne Hilton

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**From:** Layne Hilton  
**Sent:** Thursday, December 03, 2020 11:49 AM  
**To:** lockardv@gtlaw.com  
**Cc:** harkinss@gtlaw.com; GreeneJ@gtlaw.com; JPriselac@duanemorris.com; Valsartan PEC; Adam Slater; Conlee Whiteley; rubhon@gmail.com; David J. Stanoch; Behram Parekh  
**Subject:** In re Valsartan, Losartan, Irbesartan (Improperly Withheld Documents)

Victoria:

I write regarding Teva's document production.

As of Plaintiffs' review, Teva has withheld 34,259 documents on the basis of "Other Product(s). These 34,259 documents are out of 157,575 documents produced to date. More troubling than the volume, many of these documents appear to be highly relevant to the core issues in this case.

To demonstrate the fallacy of Teva's relevancy determination that these documents are about "other drugs" (and consequently not responsive), Plaintiffs identify a mere sampling of these withheld documents (including identifying the withheld document's file name taken from the metadata):

### Documents about Nitrosamine Impurities

- TEVA-MDL2875-00106924 (withheld document titled 01 Statement-Irbesartan ID5455 (TIG )-NNDMA NNDEA and other nitrosoamines to customers final.pdf)
- TEVA-MDL2875-00106927 (withheld document titled 02 Customer Statemen-NDMA-NDEA-NMBA-DIPNA-EIPNA Irbesartan-7411-TIM-EU Market.pdf)
- TEVA-MDL2875-00105237 (withheld document titled 04 Statment-Irbesartan ID7411 (TIG) NNDMA NNDEA and other nitrosoamines to customers final.pdf)
- TEVA-MDL2875-00190058 (withheld document titled 04\_Exhibit-2A-IV\_Nitrosamine solubility information.pdf)
- TEVA-MDL2875-00190059 (withheld document titled 05\_Exhibit-2A-V\_Nitrosamines IN-QA-SOP-037.pdf)
- TEVA-MDL2875-00190067 (withheld document titled 09\_Exhibit-2A-IX\_results of nitrosamine impurity.pdf)
- TEVA-MDL2875-00236765 (withheld document titled 1910 EMA information on nitrosamines\_V0.1 .pdf)
- TEVA-MDL2875-00024590 (withheld document titled N-NITROSAMINE IMPURITY ASSESSMENT REPORT.PDF)
- TEVA-MDL2875-00096689 (withheld document titled N-NDMA Valsartan (7611) Result- TIG (Year-2018).docx)
- TEVA-MDL2875-00067875 (withheld document titled NDEA in Valsartan Mylan Sperrungen 06.11.2018.xlsx)
- TEVA-MDL2875-00113500 (withheld document titled NDEA Method Validation Report.pdf)
- TEVA-MDL2875-00120889 (withheld document titled NDEA results of sartans.pdf)
- TEVA-MDL2875-00153996 (withheld document titled NDMA)
- TEVA-MDL2875-00171808 (withheld document titled NDMA - FOLLOW UP TO MAY 11 MTG)
- TEVA-MDL2875-00120882 (withheld document titled NDMA results of Sartans\_xlsx.pdf)
- TEVA-MDL2875-00040012 (withheld document titled NDMA Risk Assessment ME PTG.pdf)
- TEVA-MDL2875-00209262 (withheld document titled NDMA statement-TMS.pdf)
- TEVA-MDL2875-00110649 (withheld document titled Nitrosamine Questionnaire-Teva-Filled Questionnaire.pdf)
- TEVA-MDL2875-00074834 (withheld document titled Nitrosamines Steering Committee 13Dec19.doc)
- TEVA-MDL2875-00099046 (withheld document titled Nitrosamines Update -Jan 13 2020.pptx)
- TEVA-MDL2875-00163106 (withheld document titled Nitrosamines\_Questionnaire\_2019-11-18\_Actavis.pdf)
- TEVA-MDL2875-00443291 (withheld document titled Risk Assessment\_Valsartan\_NDMA\_NDEA.PDF)
- TEVA-MDL2875-00441836 (withheld document titled Risk from NDMA remains low, a related substance NDEA also being investigated.pdf)

- TEVA-MDL2875-00414483 (withheld document titled Toxicological Assessment for N-Nitrosodiethylamine (NDEA) in Valsartan 14Nov2018.pdf)
- TEVA-MDL2875-00414481 (withheld document titled valsaratan\_NDEA Evaluation-28112018.pdf)

**Documents about Valsartan**

- TEVA-MDL2875-00081768 (withheld document titled 02095\_AmlodValsHCTZ\_PiPPI\_E7\_15FPL.pdf)
- TEVA-MDL2875-00077404 (withheld document titled 02095\_AmlodValsHCTZ\_PiPPI\_E7\_15FPL.pdf)
- TEVA-MDL2875-00081769 (withheld document titled 02096\_AmlodValsHCTZ\_3PPI\_D7\_15FPL.pdf)
- TEVA-MDL2875-00103797 (withheld document titled 02 VALSARTAN STATMENT (ID-2895)-TIG.pdf)
- TEVA-MDL2875-00435185 (withheld document 066-CM-Valsartan hydrochlorothiazide rev B - Controlled Copy.pdf)
- TEVA-MDL2875-00324536 (withheld document titled 081718- Teva Valsartan HCTZ Tablets - Wholesaler and Retailer Recall Notices.pdf)
- TEVA-MDL2875-00164902 (withheld document titled 12534\_AMV\_Valsartan\_GCMS\_Protocol v1 -new..pdf)
- TEVA-MDL2875-00170802 (withheld document titled 174k0034-VALSARTAN-7611002016-41E255700.pdf)
- TEVA-MDL2875-00133709 (withheld document titled 2012-11 205210-1 ValasartanTabs,USP 40mg30s(LBL)VendorProof.pdf)
- TEVA-MDL2875-00133710 (withheld document titled 2012-11 205215-1 ValasartanTabs,USP 80mg1000s(LBL)VendorProof.pdf)
- TEVA-MDL2875-00156216 (withheld document titled 2012-12 208800 ValsartanTablets(PI)VendorProof.pdf)
- TEVA-MDL2875-00156215 (withheld document titled 2012-12 208801 ValsartanTablets(PatientInfo)VendorProof.pdf)
- TEVA-MDL2875-00399515 (withheld document titled 2017-05 Audit Report Request Valsartan.pdf)
- TEVA-MDL2875-00044997 (withheld document titled Vlasartan\_Mylan\_06.11.xlsx)
- TEVA-MDL2875-00138976 (withheld document titled VLN batches to Teva.pdf)
- TEVA-MDL2875-00135690 (withheld document titled Valsartan-VST Vs VAA-comparison.doc)
- TEVA-MDL2875-00441743 (withheld document titled VALSARTAN, ZHEJIANG HUAHAI PHARM.China, 01D\_C5523-16-084 0969-08.06.2016.pdf)
- TEVA-MDL2875-00290906 (withheld document titled Valsartan Update.pptx)
- TEVA-MDL2875-00350872 (withheld document titled Valsartan Update Meeting)
- TEVA-MDL2875-00441713 (withheld document titled VALSARTAN TIN FREE ZHEJIANG HUAHAI PHARM.China 01D\_C5523-17-182 1311 21.07.2017.pdf)
- TEVA-MDL2875-00183847 (withheld document titled Valsartan Timeline 10-23-12.pdf)
- TEVA-MDL2875-00101250 (withheld document titled Valsartan return to Huahai – Instructions)
- TEVA-MDL2875-00141673 (withheld document titled Valsartan Assessment report.pdf)
- TEVA-MDL2875-00461505 (withheld document titled Valsartan - HUAHAI 31-12-2018 - Q4\_18-2-2019\_FINAL02.xlsx)
- TEVA-MDL2875-00140418 (withheld document titled Valsartan - Huahai.pdf)
- TEVA-MDL2875-00430890 (withheld document titled Valsartan - customers notification- Azid process Jan2010.pdf)

**Documents about of Teva's Valsartan API Suppliers**

- TEVA-MDL2875-00137878 (withheld document titled "#177267\_Mylan Labs Ltd., Unit-VIII\_12th Nov 2018\_Audit Agenda.pdf")
- TEVA-MDL2875-00446731 (withheld document titled 186960 - Zhejiang Huahai\_QTA-16 (Snezhana).pdf)
- TEVA-MDL2875-00268426 (withheld document titled 2012-07-16 Matrix name change to Mylan.pdf)
- TEVA-MDL2875-00112814 (withheld document titled 2018 -TSA-009 Site Risk Assessment Protocol - Zhejiang Hauhai Pharmaceutical.pdf)
- TEVA-MDL2875-00407196 (withheld document titled 2018-GQ-019-1\_Zhejiang Huahai Pharmaceutical Co. Ltd \_Risk Assessment Pr....pdf)

- TEVA-MDL2875-00247578 (withheld document titled 2018-GQ-019\_Zhejiang Huahai Pharmaceutical Co. Ltd \_Risk Assessment Prot....pdf)
- TEVA-MDL2875-00367996 (withheld document titled 2018-GQ-019\_Zhejiang Huahai Pharmaceutical Co. Ltd \_Risk Assessment Protocol\_.pdf)
- TEVA-MDL2875-00367997 (withheld document titled 2018-GQ-019\_Zhejiang Huahai Pharmaceutical Co. Ltd \_Risk Assessment Protocol\_.xls)
- TEVA-MDL2875-00407194 (withheld document titled 2018-GQ-019\_Zhejiang Huahai Pharmaceutical Co. Ltd \_Risk Assessment Protocol\_CH.pdf)
- TEVA-MDL2875-00233488 (withheld document titled 2018-GQ-032\_Zhejiang Huahai Pharmaceutical Co. Ltd- Chuannan \_Risk Assessment Protocol\_.pdf)
- TEVA-MDL2875-00442024 (withheld document titled 2018-GQ-032\_Zhejiang Huahai Pharmaceutical Co. Ltd- Chuannan \_Risk Assessment Protocol\_.pdf)
- TEVA-MDL2875-00410075 (withheld document titled 2018-GQ-034\_Mylan - Andhra Pradesh \_Risk Assessment Protocol\_.pdf)
- TEVA-MDL2875-00414575 (withheld document titled 2018-GQ-034\_Mylan - Andhra Pradesh \_Risk Assessment Protocol\_.xls)
- TEVA-MDL2875-00279425 (withheld document titled 2018-GQ-034\_Mylan - Andhra Pradesh \_Risk Assessment Protocol\_signed.pdf)
- TEVA-MDL2875-00063200 (withheld document titled 2019-GQ-033\_Zhejiang Huahai Pharmaceutical Co Ltd ( Xunqiao site)- Assessment Protocol.pdf)
- TEVA-MDL2875-00415620 (withheld document titled 2019-GQ-033\_Zhejiang Huahai Pharmaceutical Co Ltd ( Xunqiao site)- Assessment Protocol\_.xls)
- TEVA-MDL2875-00398511 (withheld document titled Not acceptable suppliers - by Global QA (reviewed Igor 23.02.2015).xls)
- TEVA-MDL2875-00414647 (withheld document titled Note to File Mylan reaudit scheduled for July 1st 2019.docx)
- TEVA-MDL2875-00112717 (withheld document titled Zhejiang Huahai Pharmaceutical Co. Ltd-Chuannan \_Risk Assess.pdf)
- TEVA-MDL2875-00084964 (withheld document titled Zhejiang Huahai Chuannan China Request for Enhanced Supervision - Actavis Group PTC ehf.)
- TEVA-MDL2875-00148917 (withheld document titled Zhejiang Huahai Pharmaceutical Co. Ltd., Linhai, China 8.3.18 483\_FDA inspection.pdf)
- TEVA-MDL2875-00442002 (withheld document titled Zhejiang Huahai - NC letter with terms and conditions (Actavis).pdf)
- TEVA-MDL2875-00274899 (withheld document titled Zhejiang Huahai - NC letter with terms and conditions (Teva).pdf)

***Documents about inspections of Teva's Finished Dose Facilities where Valsartan was manufactured and/or tested:***

- TEVA-MDL2875-00446478 (withheld document titled 2012 Hal Far (Arrow) Malta FDA 483.pdf)
- TEVA-MDL2875-00446481 (withheld document titled 2010 Jerusalem OSD FDA 483 Response .pdf)
- TEVA-MDL2875-00446472 (withheld document titled 2011 Jerusalem FDA WL.pdf)
- TEVA-MDL2875-00171525 (withheld document titled 2015 Jerusalem OSD FDA 483 Response.pdf)
- TEVA-MDL2875-00400827 (withheld document titled 2015 Jerusalem OSD FDA 483 Response.pdf)
- TEVA-MDL2875-00171526 (withheld document titled 2015 Jerusalem OSD FDA 483.pdf)

The above-list is merely demonstrative and in no way meant to be exhaustive of all improperly withheld documents. Given the sheer volume of the universe of documents withheld as "Other Product(s)" (essentially 1 out of every 5 documents produced), Plaintiffs cannot (and should not) be required to go through and challenge each and every one of the 34,259 documents.

As such, Plaintiffs ask Teva to re-produce these 34,259 documents marked as “Withheld – Other Product(s)” in full, and to do so immediately.

Plaintiffs are available to meet and confer with Teva prior to next week’s Case Management Conference, such that the Parties can raise any outstanding issues regarding Teva’s improper relevance review with the Court.

Best,

Layne

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New Orleans, LA 70130  
(504) 524-5777 voice  
(504) 524-5763 fax  
[www.kanner-law.com](http://www.kanner-law.com)

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THIS EMAIL MESSAGE IS FOR THE SOLE USE OF THE INTENDED  
RECIPIENT(S) AND MAY CONTAIN CONFIDENTIAL AND PRIVILEGED  
INFORMATION. IF YOU ARE NOT THE INTENDED RECIPIENT,  
PLEASE CONTACT THE SENDER BY REPLY EMAIL AND DESTROY  
ALL COPIES OF THE ORIGINAL MESSAGE. \_\_\_\_\_

## Exhibit F

## Layne Hilton

---

**From:** Layne Hilton  
**Sent:** Friday, December 04, 2020 11:48 AM  
**To:** 'Goldberg, Seth A. (SAGoldberg@duanemorris.com)'; 'JPriselac@duanemorris.com'  
**Cc:** 'Ferretti, Joseph S.'; Conlee Whiteley; 'Adam Slater'; rubhon@gmail.com; 'Daniel Nigh'; 'Valsartan PEC'; David J. Stanoch; 'Behram Parekh'  
**Subject:** RE: In re Valsartan, Losartan and Irbesartan (Jun Du Custodial File Production)

Counsel:

I write following up on my email of December 3, 2020. Plaintiffs have now discovered a fifth email address which appears to have been utilized by Mr. Du for responsive business communications related to the issues in this case: [REDACTED]@hotmail.com.

Plaintiffs' concerns about business communications occurring on personal email accounts have now expanded in scope. Plaintiffs have subsequently confirmed that there are at least three other custodians (in addition to Mr. Du) who have responsive documents that were sent and/or received by private email accounts.

- Remonda Gergis appeared to be receiving emails at [REDACTED]@yahoo.com beginning as early as 2010, and continuing on until as recently as 2018 (when Remonda Gergis's yahoo email account appeared to be receiving emails related to the destruction of ZHP product).
- Min Li appeared to be receiving and/or sending emails at [REDACTED]@yahoo.com from 2015 until 2019, including communications with Charles Wang, a toxicologist (and subpoena target) employed by ZHP to conduct an analysis of the toxicological profile of NDMA.
- Eric Tsai appeared to be sending and/or receiving emails from [REDACTED]@hotmail.com from 2010 until 2020, including communications regarding the scale-up of the Valsartan API manufacturing process from as early as 2010.

Moreover, the practice of using personal email accounts appears to be commonplace amongst ZHP employees. In some communications, ZHP employees direct API customers to their personal email addresses. See TORRENT-MDL2875-00439144 (in an email discussing the purchase of Valsartan API, ZHP employee Liu Yao told a Torrent employee, "if any failure for email sending, pls kindly send your email to my personal email box [REDACTED]@hotmail.com").

In fact, many ZHP employees actually include their personal and/or private email addresses in their company email signature block:

**Rose Zhu**

**Zhejiang Huahai Pharmaceutical Co., Ltd.**

Shanghai Base: [REDACTED]

Linhai HQ Base: [REDACTED]

Mobile: +86 18 [REDACTED]

Hotmail: [REDACTED]@hotmail.com

See TORRENT-MDL2875-00437928

Sales Department

Zhejiang Huahai Pharmaceutical Co., Ltd

Xunqiao, Linhai, Zhejiang 317024 China

Tel: [REDACTED]

E-mail: [REDACTED]@huahaipharm.com

MSN: [REDACTED]@hotmail.com

See TEVA-MDL2875-00228280

Phone: [REDACTED]

Mobile: [REDACTED]

E-mail: [REDACTED]@huahaipharm.com

If any failure for email sending, pls kindly send your email to my private email box:

[REDACTED]@hotmail.com

See TORRENT-MDL2875-00439166.

At no point during the informal ESI discussions at the outset of this case were Plaintiffs informed that ZHP had a business practice of allowing employees to utilize personal email addresses to communicate with internal and external parties. However, it is now obvious that the company actually condoned employees' use of personal and/or private email accounts for business communications.

Plaintiffs must understand the implications of this widespread practice on ZHP's document collection, and how ZHP is collecting these responsive emails for custodial file production. More pressing, Plaintiffs must also know if ZHP employees were explicitly instructed to preserve emails maintained in these private email accounts pursuant to any of litigation notices sent on behalf of Mr. Du from September 13, 2018 to December 21, 2019.

Please inform Plaintiffs when ZHP is available to meet-and-confer either on Monday or Tuesday of next week. Given the urgency of this issue and its ramifications on forthcoming productions expected from custodians in China by the end of the year, the Parties must resolve this issue related to private email accounts immediately.

Best,

Layne

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**From:** Layne Hilton

**Sent:** Thursday, December 03, 2020 2:53 PM

**To:** Goldberg, Seth A. (SAGoldberg@duanemorris.com) <SAGoldberg@duanemorris.com>; JPriselac@duanemorris.com

**Cc:** Ferretti, Joseph S. <JSFerretti@duanemorris.com>; Conlee Whiteley <c.whiteley@kanner-law.com>; Adam Slater <ASlater@mazieslater.com>; rubhon@gmail.com; Daniel Nigh <dnigh@levinlaw.com>; Valsartan PEC <valpec@kirtlandpackard.com>; David J. Stanoch <d.stanoch@kanner-law.com>; Behram Parekh <behran.parekh@drlawllp.com>

**Subject:** In re Valsartan, Losartan and Irbesartan (Jun Du Custodial File Production)

Counsel:

I write regarding the custodial file production for Jun Du.

As ZHP is no doubt aware, Jun Du was identified by Plaintiffs as a priority custodian as early as this summer. Given the fact Mr. Du is located in the United States, ZHP represented that Mr. Du's custodial file production would not be subject to the additional Chinese State Secret document review that would necessitate additional time for production. In light of the ongoing discussions with Counsel regarding appropriate deponents, Plaintiffs initiated a review of Mr. Du's custodial production.

Plaintiffs have identified the following serious deficiencies with the custodial production for Mr. Du. First, of Mr. Du's total custodial production of 1,391 documents, Plaintiffs could only locate a scant 366 emails (meant to cover the totality of Mr. Du's responsive emails from 2010 to present). In analyzing these emails, 87 (out of 366) of these emails were actually withheld in their entirety on the basis of "Other Product(s)," despite having responsive documents (which were subsequently produced) attached to it. Plaintiffs identify the bates ranges for these documents in the attached.

Further, Mr. Du's emails only begin as of March 1, 2017, despite the fact that Mr. Du began at ZHP well before the relevant time period start date of 2010. See ZHP00002144.

Potentially explaining the paucity of emails contained within Mr. Du's custodial file production, Plaintiffs noted that most (if not all) emails in Mr. Du's custodial file are from [REDACTED]@princetonpharm.com. However, in reviewing the custodial productions of other ZHP custodians, it is obvious that Jun Du has been utilizing a variety of email addresses to communicate about business matters.

These additional email addresses which appear to be associated with Mr. Du are as follows:

- [REDACTED]@gmail.com
  - There appear to be over 2,000 relevant, responsive email communications that were produced in the custodial files of other custodians which sent emails to this email account. None of these emails were produced as part of Mr. Du's custodial production. These include not only email communications internally with other ZHP employees, but also communications with the FDA, and with third-party consultants (such as Dr. Zi-Qiang Gu, the subject of a pending subpoena).
  - Only 50 of these emails appear in Mr. Du's custodial production, and only appear to have been captured because the email was forwarded to the above-referenced princetonpharm email account
- [REDACTED]@gmail.com
  - There are approximately 6 emails sent to this email account address. None of these emails appear in Mr. Du's custodial file production.
- [REDACTED]@huahaipharmus.com
  - There are two emails sent to this particular account, both from 2010. Neither of these emails appear in Mr. Du's custodial file production.
- [REDACTED]@huahaipharm.com
  - There are over 100 emails that were sent to this email account spanning 2014 to present, only 4 of which were produced in Mr. Du's custodial file (and appear there because it was ultimately forwarded to Mr. Du's princetonpharm email account.

Plaintiffs request that ZHP explain the following:

- Were these additional email accounts associated with Mr. Du (and with which Mr. Du was clearly using for company purposes) searched for responsive documents?
- If these email accounts were searched and collected, why were the email communications not produced as part of Mr. Du's custodial production?
- If these email accounts were not searched and collected, when does ZHP anticipate searching and collecting these email accounts?
- For the 366 emails ZHP did produce as part of Mr. Du's custodial file production, why did ZHP withhold 88 of these emails, when they obviously contained attachments ZHP deemed were relevant?

Please let me know when ZHP is prepared to meet-and-confer regarding the above.

Best,

Layne

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PLEASE CONTACT THE SENDER BY REPLY EMAIL AND DESTROY  
ALL COPIES OF THE ORIGINAL MESSAGE. \_\_\_\_\_

## Exhibit G

## Layne Hilton

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**From:** Frank H. Stoy <FHS@Pietragallo.com>  
**Sent:** Saturday, December 05, 2020 11:57 AM  
**To:** Layne Hilton  
**Cc:** Clem C. Trischler; Jason M. Reefer; Valsartan PEC; JPriselac@duanemorris.com; Conlee Whiteley; Adam Slater; Daniel Nigh; David J. Stanoch; rubhon@gmail.com; Behram Parekh  
**Subject:** Re: In re Valsartan - Improperly Withheld Documents

Layne,

We are in receipt of your email correspondence alleging deficiencies in Mylan's custodial document production. As you are aware, the documents that Plaintiffs have identified are subject to the agreement between the parties that non-responsive family members of responsive documents may be withheld from production. This agreement was mutually beneficial as it allowed Defendants to avoid the time and expense of manually redacting non-responsive information, but also enabled Plaintiffs to avoid having to sift through thousands of irrelevant documents.

As a threshold matter, Plaintiffs cannot discern based solely on the title of a document that it was improperly withheld. By way of investigation, I have personally reviewed the 44 exemplars you identify below. Without delving into our work product, suffice to say that many of the exemplar documents Plaintiffs have identified as "highly relevant to the core issues in this case" were properly coded non-responsive. Specifically, many of these documents date from early 2019 to the present. As Plaintiffs are aware, subsequent to the global recall of sartan-containing medications in 2018 by various pharmaceutical manufacturers around the world, FDA and other regulatory agencies began to require widespread nitrosamine testing of medications and raw materials on an ongoing basis, and not limited to valsartan. As confirmed by FDA's most recent nitrosamine-related guidance, these requirements remain in effect. Mylan's product portfolio contains thousands of medications, many of which are now being routinely tested for nitrosamine impurities. Several of the documents Plaintiffs identify below as "highly relevant" fall into this category and were properly withheld because they do not relate to the valsartan at issue in this litigation.

Further, even to the extent some of the documents that Plaintiffs have identified below are arguably responsive, I can confirm that identical versions of these documents have also been produced in full, in most instances numerous times, elsewhere in Mylan's production. For example, you assert that MYLAN-MDL2875-00573802 was improperly withheld. I can confirm, however, that this document was produced in full at MYLAN-MDL2875-00037661. Thus, even to the extent the document was mistakenly withheld in one instance, there is no prejudice to Plaintiffs. The same applies to MYLAN-MDL2875-00301339 (*see* MYLAN-MDL2875-00212372), MYLAN-MDL2875-00275069 (*see* MYLAN-MDL2875-00242924), MYLAN-MDL2875-00344253 (*see* MYLAN-MDL2875-00244567), MYLAN-MDL2875-00396840 (*see* MYLAN-MDL2875-00562354), MYLAN-MDL2875-00270210 (*see* MYLAN-MDL2875-00287887), and MYLAN-MDL2875-00506150 (*see* MYLAN-MDL2875-00506140). This is unsurprising given the high level of overlap in Mylan's document collection.

Only a small fraction of the documents identified by Plaintiffs (MYLAN-MDL2875-00301437, MYLAN-MDL2875-00523823, MYLAN-MDL2875-00468154, MYLAN-MDL2875-00521922, MYLAN-MDL2875-00530121, MYLAN-MDL2875-00396866, and MYLAN-MDL2875-00383783), appear to have been withheld in error and not otherwise produced. Mylan will agree to include these documents in a supplemental production.

Finally, one of the documents you identified below, MYLAN-MDL2875-00573800, was marked responsive and already produced in full.


To date, Mylan has conducted a good faith, eyes-on review of millions of documents in accordance with the ESI protocol and the Orders of Court. While we are confident that the review has been conducted appropriately, we will

independently undertake a secondary review of the document set you have identified, and we will make a supplemental production if warranted.

Thanks,  
Frank

**Frank H. Stoy, Esquire**

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38th Floor, One Oxford Centre  
Pittsburgh, PA 15219  
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Connect with me on LinkedIn: 



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---

**From:** Layne Hilton <l.hilton@kanner-law.com>

**Date:** Wednesday, December 2, 2020 at 5:39 PM

**To:** "Clem C. Trischler" <CCT@Pietragallo.com>

**Cc:** "Jason M. Reefer" <JMR@Pietragallo.com>, Frank Stoy <FHS@Pietragallo.com>, Valsartan PEC <valpec@kirtlandpackard.com>, "JPriselac@duanemorris.com" <JPriselac@duanemorris.com>, Conlee Whiteley <c.whiteley@kanner-law.com>, Adam Slater <ASlater@mazieslater.com>, Daniel Nigh <dnigh@levinlaw.com>, "David J. Stanoch" <d.stanoch@kanner-law.com>, "rubhon@gmail.com" <rubhon@gmail.com>, Behram Parekh <behram.parekh@drlawllp.com>

**Subject:** In re Valsartan - Improperly Withheld Documents

Clem –

I write regarding Mylan's document production

As of my review, Mylan has withheld a staggering 45,036 documents from production on the basis of "other drug/non-responsive." These 45,036 documents are out of 163,597 total documents produced to date. More troubling than this, many of these documents appear to be **highly relevant to the core issues in this case**.

To demonstrate the fallacy of Mylan's relevancy determinations, Plaintiffs have identified just a mere sampling of the documents (including the document's file name taken from the metadata) which Mylan deemed "non-responsive" and consequently withheld from production:

***Documents regarding NDMA and NDEA:***

- MYLAN-MDL2875-00573802 (withheld document titled NDMA & NDEA Study Protocol)
- MYLAN-MDL2875-00573800 (withheld document titled NDMA & NDEA Study Report)
- MYLAN-MDL2875-00573801 (withheld document titled NDMA & NDEA Study Analytical Reports)
- MYLAN-MDL2875-00358255 (withheld document titled NDMA & NDEA Study Report – Addendum)

- MYLAN-MDL2875-00301339 (withheld document titled NDMA and NDEA content in Valsartan\_AMT Protocol.docx)
- MYLAN-MDL2875-00368316 (withheld document titled document titled NDMA Declaration.pdf)
- MYLAN-MDL2875-00368315 (withheld document titled NDEA Declaration.pdf)
- MYLAN-MDL2875-00275069 (withheld document titled NDEA, NDIA, NDMA Characterisation reports)
- MYLAN-MDL2875-00507589 (withheld document titled NDEA Impurity.pdf)
- MYLAN-MDL2875-00368106 (withheld document titled ndea\_and\_ndma\_detection\_in\_sartan\_containing\_tablets\_by\_lc-ms-ms.pdf)
- MYLAN-MDL2875-00344253 (withheld document titled NDMA, NDEA, NEIA and NDIA Content by GC-MS AMV Report.pdf)
- MYLAN-MDL2875-00303186 (withheld document titled Nitrosamine Assessment Reports Summary Across MLL API Network\_Final Copy (003).docx)
- MYLAN-MDL2875-00472554 (withheld document titled Nitrosamine Risk Assessment\_Valsartan Tablets.docx)
- MYLAN-MDL2875-00447843 (withheld document titled Nitroso impurities-current status -16042019.xlsx)

***Documents regarding the EMA's investigation into the Valsartan Nitrosamine Contamination:***

- MYLAN-MDL2875-00471611 (withheld document titled Sartans Art 31 – CHMP opinion.doc)
- MYLAN-MDL2875-00507121 (withheld document titled Sartans Art 41 – CHMP timetable.doc)
- MYLAN-MDL2875-00311562 (withheld document titled sartans-article-31-referral-chmp-list-questions-be-addressed-api-manufacturers-valsartan-containing\_en.pdf\_)
- MYLAN-MDL2875-00471276 (withheld document titled Sartans Art 31 – Appendix 2 to CHMP opinion – CHMP AR.docx)

***Documents regarding the Valsartan API manufacturing process:***

- MYLAN-MDL2875-00268231 (withheld document titled VLN-2 BBS-B.doc)
- MYLAN-MDL2875-00268229 (withheld document titled VLN-2 B PB-10.doc)
- MYLAN-MDL2875-00268232 (withheld document titled VLN-2BBS—A.doc)
- MYLAN-MDL2875-00268252 (withheld document titled VST Validation costing.pdf)
- MYLAN-MDL2875-00463841 (withheld document titled VST-1-INP.doc)

***Documents regarding the recovered solvents used in the manufacture of Valsartan which resulted in the production of NDEA and the vendors who supply Mylan with recovered solvents:***

- MYLAN-MDL2875-00301437-38 (email regarding “queries from FDA” which attaches a document describing the risks of NDEA formation in recovered o-xylene, and attaches 7 exemplar chromatograms (all withheld) for the recovered o-xylene).
- MYLAN-MDL2875-00431839 (withheld document titled O-Xylene GC Chromatorrams [sic])
- MYLAN-MDL2875-00523823 (withheld document titled O-Xylene Recover (VST)-Unit-8.pdf)
- MYLAN-MDL2875-00468154 (withheld document titled O-Xylene VST-VLS-II.pdf)
- MYLAN-MDL2875-00521922 (withheld document titled Valsartan – Lantech.pdf)
- MYLAN-MDL2875-00565036 (withheld document titled Lantech Valsatran status.xls[sic])
- MYLAN-MDL2875-00396840 (withheld document titled Lantech VLN & VST 2.pdf)
- MYLAN-MDL2875-00562623 (withheld document titled Lantech 2011-2019.xlsx)
- MYLAN-MDL2875-00530121 (withheld document titled Lantech Notification.pdf)
- MYLAN-MDL2875-00396866 (withheld document titled Lantech.Valsartan (VLN) II from Crude Valsartan (VLN) II RE.Rev.03.pdf)

***Documents regarding testing and/or data issues specific to Valsartan and/or recovered solvents used in Valsartan***

- MYLAN-MDL2875-00471146 (withheld document titled Valsartan API Data nashik recovered solvents.xlsx)
- MYLAN-MDL2875-00507240 (withheld document titled Valsartan API batches – requested by customers to check NDEA – revised)
- MYLAN-MDL2875-00531238 (withheld document titled Valsartan Data.xls)

- MYLAN-MDL2875-00383783 (withheld document titled Valsartan impurities.pdf[sic])
- MYLAN-MDL2875-00270210 (withheld document titled valsartan initial chromatography part 2 of 2.pdf[sic])
- MYLAN-MDL2875-00509570 (withheld document titled NOTIFICATION OOS\_Valsartan HCTZ 2015.pdf)

***Documents regarding the facilities where Valsartan was manufactured:***

- MYLAN-MDL2875-00403234 (withheld document titled U-3 March Monthly Report 2011.doc)
- MYLAN-MDL2875-00558287 (withheld document titled Unit-3\_MIS report-June 11.xls)
- MYLAN-MDL2875-00506150 (withheld document titled USFDA EIR Report\_2014 which appears to be about Unit III)
- MYLAN-MDL2875-00570994 (withheld document titled USFDA\_EIR\_2018.pdf which appears to be about Unit 8)
- MYLAN-MDL2875-00466782 (withheld document titled Unit-8.docx)

The above-list is merely demonstrative and in no way meant to be exhaustive of all improperly withheld documents. Given the sheer volume of the universe of withheld documents (essentially 1 out of every 4 documents produced), Plaintiffs cannot (and should not) be required to go through and challenge each and every one of the 45,036 documents.

As such, Plaintiffs ask Mylan to re-produce all 45,036 documents withheld as “non-responsive” in full, and to do so immediately.

Plaintiffs are available to meet and confer with Mylan prior to next week’s Case Management Conference, such that the Parties can raise any outstanding issues regarding Mylan’s improper relevance review with the Court.

Best,

Layne

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## Exhibit H

**Layne Hilton**

---

**From:** harkinss@gtlaw.com  
**Sent:** Tuesday, December 08, 2020 4:02 PM  
**To:** lockardv@gtlaw.com; Layne Hilton  
**Cc:** GreeneJ@gtlaw.com; JPriselac@duanemorris.com; valpec@kirtlandpackard.com; ASlater@mazieslater.com; Conlee Whiteley; rubhon@gmail.com; David J. Stanoch; behram.parekh@drlawllp.com  
**Subject:** RE: In re Valsartan, Losartan, Irbesartan (Improperly Withheld Documents)

Layne,

We write in response to the below correspondence on alleged deficiencies in Teva's document production to date. As a preliminary matter, given that the ESI protocol requires review and production of full families and Teva is involved in the manufacture of hundreds of medications outside the scope of this litigation, it should not come as a surprise to any party that a substantial number of documents within families containing some responsive material relate solely to irrelevant "Other Products." Many of these documents were withheld based on the explicit agreement with Plaintiffs' counsel that Defendants may withhold irrelevant "Other Product" documents which would generate thousands of pages of material unrelated to Valsartan. It is also notable that file names which indicate "Valsartan" or "nitrosamines" do not necessarily correlate to responsive material, particularly with regard to Teva, which recalled all its US Valsartan product and discontinued its sale of Valsartan to the United States in 2018, including product not affected by nitrosamines due to commercial reasons.

With respect to the documents identified in your correspondence, Teva has conducted a second review of each of the 80 documents. Though Teva does not waive any claims of attorney work product in making this representation, the vast majority of unique documents identified in your correspondence – 49 of 80 – are non-responsive. Of the remaining 31 documents, 25 identified duplicate files which had in fact already been produced to Plaintiffs. For example, six documents – the entirety of the subheading "Documents about inspections of Teva's Finished Dose Facilities where Valsartan was manufactured and/or tested" – are duplicates of documents previously produced in connection with the non-custodial core discovery production. The nine responsive documents within the subheading "Documents about of Teva's Valsartan API Suppliers" are all duplicates of documents produced at TEVA-MDL2875-00194315, 00437492, 00442747, and 00442748.

In addition, the ten other duplicative documents identified in the below chart are responsive and will be produced. Teva notes once again that all of these documents are duplicates of documents produced elsewhere (in many instances multiple times) at the location referenced below for your convenience. With respect to these documents and the above duplicates, there can obviously be no prejudice to Plaintiffs as this material was in fact timely produced.

**DOCUMENTS IDENTIFIED BY PLAINTIFFS AS IMPROPERLY WITHHELD**

	BATES LABEL	DESCRIPTION/FILE NAME	PLAIN
1.	TEVA-MDL2875-00106924	01 Statement-Irbesartan ID5455 (TIG )-NNDMA NNDEA and other nitrosoamines to customers final.pdf	Document Nitrosami
2.	TEVA-MDL2875-00106927	02 Customer Statemen-NDMA-NDEA-NMBA-DIPNA-EIPNA Irbesartan-7411-TIM-EU Market.pdf	Document Nitrosami
3.	TEVA-MDL2875-00105237	04 Statment-Irbesartan ID7411 (TIG) NNDMA NNDEA and other nitrosoamines to customers final.pdf	Document Nitrosami

	BATES LABEL	DESCRIPTION/FILE NAME	PLAIN
4.	TEVA-MDL2875-00190058	04_Exhibit-2A-IV_Nitrosamine solubility information.pdf	Document Nitrosami
5.	TEVA-MDL2875-00190059	05_Exhibit-2A-V_Nitrosamines IN-QA-SOP-037.pdf	Document Nitrosami
6.	TEVA-MDL2875-00190067	09_Exhibit-2A-IX_results of nitrosamine impurity.pdf	Document Nitrosami
7.	TEVA-MDL2875-00236765	1910 EMA information on nitrosamines_V0.1 .pdf	Document Nitrosami
8.	TEVA-MDL2875-00024590	N-NITROSAMINE IMPURITY ASSESSMENT REPORT.PDF	Document Nitrosami
9.	TEVA-MDL2875-00096689	N-NDMA Valsartan (7611) Result- TIG (Year-2018).docx	Document Nitrosami
10.	TEVA-MDL2875-00067875	NDEA in Valsartan Mylan Sperrungen 06.11.2018.xlsx	Document Nitrosami
11.	TEVA-MDL2875-00113500	NDEA Method Validation Report.pdf	Document Nitrosami
12.	TEVA-MDL2875-00120889	NDEA results of sartans.pdf	Document Nitrosami
13.	TEVA-MDL2875-00153996	NDMA	Document Nitrosami
14.	TEVA-MDL2875-00171808	NDMA - FOLLOW UP TO MAY 11 MTG	Document Nitrosami
15.	TEVA-MDL2875-00120882	NDMA results of Sartans_xlsx.pdf	Document Nitrosami
16.	TEVA-MDL2875-00040012	NDMA Risk Assessment ME PTG.pdf	Document Nitrosami
17.	TEVA-MDL2875-00209262	NDMA statemenNitrosamine Questionnaire-Teva-Filled Questionnaire.pdf-TMS.pdf	Document Nitrosami
18.	TEVA-MDL2875-00110649	Nitrosamine Questionnaire-Teva-Filled Questionnaire.pdf	Document Nitrosami
19.	TEVA-MDL2875-00074834	Nitrosamines Steering Committee 13Dec19.doc	Document Nitrosami
20.	TEVA-MDL2875-00099046	Nitrosamines Update -Jan 13 2020.pptx	Document Nitrosami
21.	TEVA-MDL2875-00163106	Nitrosamines_Questionnaire_2019-11-18_Actavis.pdf	Document Nitrosami
22.	TEVA-MDL2875-00443291	Risk Assessment_Valsartan_NDMA_NDEA.PDF	Document Nitrosami
23.	TEVA-MDL2875-00441836	Risk from NDMA remains low, a related substance NDEA also being investigated.pdf	Document Nitrosami
24.	TEVA-MDL2875-00414483	Toxicological Assessment for N-Nitrosodiethylamine (NDEA) in Valsartan 14Nov2018.pdf	Document Nitrosami
25.	TEVA-MDL2875-00414481	valsaratan_NDEA Evaluation-28112018.pdf	Document Nitrosami
26.	TEVA-MDL2875-00081768	02095_AmlodValsHCTZ_PiPPI_E7_15FPL.pdf	Document
27.	TEVA-MDL2875-00077404	02095_AmlodValsHCTZ_PiPPI_E7_15FPL.pdf	Document

	BATES LABEL	DESCRIPTION/FILE NAME	PLAIN
28.	TEVA-MDL2875-00081769	02096_AmlodValsHCTZ_3PPI_D7_15FPL.pdf	Documen
29.	TEVA-MDL2875-00103797	02 VALSARTAN STATMENT (ID-2895)-TIG.pdf	Documen
30.	TEVA-MDL2875-00435185	066-CM-Valsartan hydrochlorothiazide rev B - Controlled Copy.pdf	Documen
31.	TEVA-MDL2875-00324536	081718- Teva Valsartan HCTZ Tablets - Wholesaler and Retailer Recall Notices.pdf	Documen
32.	TEVA-MDL2875-00164902	12534_AMV_Valsartan _GCMS_Protocol v1 -new..pdf	Documen
33.	TEVA-MDL2875-00170802	174k0034-VALSARTAN-7611002016-41E255700.pdf	Documen
34.	TEVA-MDL2875-00133709	2012-11 205210-1 ValasartanTabs,USP 40mg30s(LBL)VendorProof.pdf	Documen
35.	TEVA-MDL2875-00133710	2012-11 205215-1 ValasartanTabs,USP 80mg1000s(LBL)VendorProof.pdf	Documen
36.	TEVA-MDL2875-00156216	2012-12 208800 ValsartanTablets(PI)VendorProof.pdf	Documen
37.	TEVA-MDL2875-00156215	2012-12 208801 ValsartanTablets(PatientInfo)VendorProof.pdf	Documen
38.	TEVA-MDL2875-00399515	2017-05 Audit Report Request Valsartan.pdf	Documen
39.	TEVA-MDL2875-00044997	Vlasartan_Mylan_06.11.xlsx	Documen
40.	TEVA-MDL2875-00138976	VLN batches to Teva.pdf	Documen
41.	TEVA-MDL2875-00135690	Valsartan-VST Vs VAA-comparison.doc	Documen
42.	TEVA-MDL2875-00441743	VALSARTAN, ZHEJIANG HUAHAI PHARM.China, 01D_C5523-16-084 0969-08.06.2016.pdf	Documen
43.	TEVA-MDL2875-00290906	Valsartan Update.pptx	Documen
44.	TEVA-MDL2875-00350872	Valsartan Update Meeting	Documen
45.	TEVA-MDL2875-00441713	VALSARTAN TIN FREE ZHEJIANG HUAHAI PHARM.China 01D_C5523-17-182 1311 21.07.2017.pdf	Documen
46.	TEVA-MDL2875-00183847	Valsartan Timeline 10-23-12.pdf	Documen
47.	TEVA-MDL2875-00101250	Valsartan return to Huahai – Instructions	Documen
48.	TEVA-MDL2875-00141673	Valsartan Assessment report.pdf	Documen
49.	TEVA-MDL2875-00461505	Valsartan - HUAHAI 31-12-2018 - Q4_18-2-2019_FINAL02.xlsx	Documen
50.	TEVA-MDL2875-00140418	Valsartan - Huahai.pdf	Documen
51.	TEVA-MDL2875-00430890	Valsartan - customers notification- Azid process Jan2010.pdf	Documen

	BATES LABEL	DESCRIPTION/FILE NAME	PLAIN
52.	TEVA-MDL2875-00137878	#177267_Mylan Labs Ltd., Unit-VIII_12th Nov 2018_Audit Agenda.pdf	Documen Valsartan
53.	TEVA-MDL2875-00446731	186960 - Zhejiang Huahai_QTA-16 (Snezhana).pdf	Documen Valsartan
54.	TEVA-MDL2875-00268426	2012-07-16 Matrix name change to Mylan.pdf	Documen Valsartan
55.	TEVA-MDL2875-00112814	2018 -TSA-009 Site Risk Assessment Protocol - Zhejiang Hauhai Pharmaceutical.pdf	Documen Valsartan
56.	TEVA-MDL2875-00407196	2018-GQ-019-1_Zhejiang Huahai Pharmaceutical Co. Ltd _Risk Assessment Pr....pdf	Documen Valsartan
57.	TEVA-MDL2875-00247578	2018-GQ-019_Zhejiang Huahai Pharmaceutical Co. Ltd _Risk Assessment Prot....pdf	Documen Valsartan
58.	TEVA-MDL2875-00367996	2018-GQ-019_Zhejiang Huahai Pharmaceutical Co. Ltd _Risk Assessment Protocol_.pdf	Documen Valsartan
59.	TEVA-MDL2875-00367997	2018-GQ-019_Zhejiang Huahai Pharmaceutical Co. Ltd _Risk Assessment Protocol_.xls	Documen Valsartan
60.	TEVA-MDL2875-00407194	2018-GQ-019_Zhejiang Huahai Pharmaceutical Co. Ltd _Risk Assessment Protocol_CH.pdf	Documen Valsartan
61.	TEVA-MDL2875-00233488	2018-GQ-032_Zhejiang Huahai Pharmaceutical Co. Ltd-Chuannan _Risk Assessment Protocol_.pdf	Documen Valsartan
62.	TEVA-MDL2875-00442024	2018-GQ-032_Zhejiang Huahai Pharmaceutical Co. Ltd-Chuannan _Risk Assessment Protocol_.pdf	Documen Valsartan
63.	TEVA-MDL2875-00410075	2018-GQ-034_Mylan - Andhra Pradesh _Risk Assessment Protocol_.pdf	Documen Valsartan
64.	TEVA-MDL2875-00414575	2018-GQ-034_Mylan - Andhra Pradesh _Risk Assessment Protocol_.xls	Documen Valsartan
65.	TEVA-MDL2875-00279425	2018-GQ-034_Mylan - Andhra Pradesh _Risk Assessment Protocol_signed.pdf	Documen Valsartan
66.	TEVA-MDL2875-00063200	2019-GQ-033_Zhejiang Huahai Pharmaceutical Co Ltd ( Xunqiao site)-Assessment Protocol.pdf	Documen Valsartan
67.	TEVA-MDL2875-00415620	2019-GQ-033_Zhejiang Huahai Pharmaceutical Co Ltd ( Xunqiao site)-Assessment Protocol_.xls	Documen Valsartan
68.	TEVA-MDL2875-00398511	Not acceptable suppliers - by Global QA (reviewed Igor 23.02.2015).xls	Documen Valsartan
69.	TEVA-MDL2875-00414647	Note to File Mylan reaudit scheduled for July 1st 2019.docx	Documen Valsartan
70.	TEVA-MDL2875-00112717	Zhejiang Huahai Pharmaceutical Co. Ltd-Chuannan _Risk Assess.pdf	Documen Valsartan
71.	TEVA-MDL2875-00084964	Zhejiang Huahai Chuannan China Request for Enhanced Supervision - Actavis Group PTC ehf.	Documen Valsartan
72.	TEVA-MDL2875-00148917	Zhejiang Huahai Pharmaceutical Co. Ltd., Linhai, China 8.3.18 483_FDA inspection.pdf	Documen Valsartan
73.	TEVA-MDL2875-00442002	Zhejiang Huahai - NC letter with terms and conditions (Actavis).pdf	Documen Valsartan
74.	TEVA-MDL2875-00274899	Zhejiang Huahai - NC letter with terms and conditions (Teva).pdf	Documen Valsartan

	BATES LABEL	DESCRIPTION/FILE NAME	PLAIN
75.	TEVA-MDL2875-00446478	2012 Hal Far (Arrow) Malta FDA 483.pdf	Document of Teva's Facilities was manu tested
76.	TEVA-MDL2875-00446481	2010 Jerusalem OSD FDA 483 Response .pdf	Document of Teva's Facilities was manu tested
77.	TEVA-MDL2875-00446472	2011 Jerusalem FDA WL.pdf	Document of Teva's Facilities was manu tested
78.	TEVA-MDL2875-00171525	2015 Jerusalem OSD FDA 483 Response.pdf	Document of Teva's Facilities was manu tested
79.	TEVA-MDL2875-00400827	2015 Jerusalem OSD FDA 483 Response.pdf	Document of Teva's Facilities was manu tested
80.	TEVA-MDL2875-00171526	2015 Jerusalem OSD FDA 483.pdf	Document of Teva's Facilities was manu tested

The documents identified at TEVA-MDL2875-00133709, TEVA-MDL2875-00133710, TEVA-MDL2875-00156216, and TEVA-MDL2875-00156215 were not previously produced and will be produced. We note that all four of these documents are marginally responsive drafts, substantively duplicative of labeling documents already produced. Finally, the two documents identified at TEVA-MDL2875-00067875 and TEVA-MDL2875-00183847 are marginally responsive and will be produced in the interest of resolving this issue.

In light of the above, we hope you will agree that Plaintiffs' request for Teva to produce over 34,000 documents is not an appropriate solution. To the extent there are further documents you feel necessitate a secondary review, Teva will, within reason, endeavor to do so. Please let us know if this response satisfies your concerns or if a meet and confer to discuss further is needed.

Best,

**Steven M. Harkins**  
Associate

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T +1 678.553.2312 | F +1 678.553.2441  
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---

**From:** Lockard, Victoria D. (Shld-Atl-LT)

**Sent:** Thursday, December 3, 2020 1:02 PM

**To:** Layne Hilton <l.hilton@kanner-law.com>

**Cc:** Harkins, Steven M. (Assoc-ATL-LT) <harkinss@gtlaw.com>; Greene, Jeffrey (Shld-Bos-LT) <GreeneJ@gtlaw.com>; JPriselac@duanemorris.com; Valsartan PEC <valpec@kirtlandpackard.com>; Adam Slater <ASlater@mazieslater.com>; Conlee Whiteley <c.whiteley@kanner-law.com>; rubhon@gmail.com; David J. Stanoch <d.stanoch@kanner-law.com>; Behram Parekh <behram.parekh@drlawllp.com>

**Subject:** RE: In re Valsartan, Losartan, Irbesartan (Improperly Withheld Documents)

Hi Layne,

Without commenting on the legitimacy of what's stated below, I'm confirming receipt. We will take a look and get back to you with a time for a call to meet & confer.

Thanks, Victoria

Victoria Davis Lockard

Shareholder

Vice-Chair, Pharmaceutical, Medical Device & Health Care Litigation

Products Liability & Mass Torts

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---

**From:** Layne Hilton <l.hilton@kanner-law.com>

**Sent:** Thursday, December 3, 2020 12:49 PM

**To:** Lockard, Victoria D. (Shld-Atl-LT) <lockardv@gtlaw.com>

**Cc:** Harkins, Steven M. (Assoc-ATL-LT) <harkinss@gtlaw.com>; Greene, Jeffrey (Shld-Bos-LT) <GreeneJ@gtlaw.com>; JPriselac@duanemorris.com; Valsartan PEC <valpec@kirtlandpackard.com>; Adam Slater <ASlater@mazieslater.com>; Conlee Whiteley <c.whiteley@kanner-law.com>; rubhon@gmail.com; David J. Stanoch <d.stanoch@kanner-law.com>; Behram Parekh <behram.parekh@drlawllp.com>

**Subject:** In re Valsartan, Losartan, Irbesartan (Improperly Withheld Documents)

**\*EXTERNAL TO GT\***

Victoria:

I write regarding Teva's document production.

As of Plaintiffs' review, Teva has withheld 34,259 documents on the basis of "Other Product(s)". These 34,259 documents are out of 157,575 documents produced to date. More troubling than the volume, many of these documents appear to be highly relevant to the core issues in this case.

To demonstrate the fallacy of Teva's relevancy determination that these documents are about "other drugs" (and consequently not responsive), Plaintiffs identify a mere sampling of these withheld documents (including identifying the withheld document's file name taken from the metadata):

**Documents about Nitrosamine Impurities**

- TEVA-MDL2875-00106924 (withheld document titled 01 Statement-Irbesartan ID5455 (TIG )-NNDMA NNDEA and other nitrosoamines to customers final.pdf)
- TEVA-MDL2875-00106927 (withheld document titled 02 Customer Statemen-NDMA-NDEA-NMBA-DIPNA-EIPNA Irbesartan-7411-TIM-EU Market.pdf)
- TEVA-MDL2875-00105237 (withheld document titled 04 Statment-Irbesartan ID7411 (TIG) NNDMA NNDEA and other nitrosoamines to customers final.pdf)
- TEVA-MDL2875-00190058 (withheld document titled 04\_Exhibit-2A-IV\_Nitrosamine solubility information.pdf)
- TEVA-MDL2875-00190059 (withheld document titled 05\_Exhibit-2A-V\_Nitrosamines IN-QA-SOP-037.pdf)
- TEVA-MDL2875-00190067 (withheld document titled 09\_Exhibit-2A-IX\_results of nitrosamine impurity.pdf)
- TEVA-MDL2875-00236765 (withheld document titled 1910 EMA information on nitrosamines\_V0.1 .pdf)
- TEVA-MDL2875-00024590 (withheld document titled N-NITROSAMINE IMPURITY ASSESSMENT REPORT.PDF)
- TEVA-MDL2875-00096689 (withheld document titled N-NDMA Valsartan (7611) Result- TIG (Year-2018).docx)
- TEVA-MDL2875-00067875 (withheld document titled NDEA in Valsartan Mylan Sperrungen 06.11.2018.xlsx)
- TEVA-MDL2875-00113500 (withheld document titled NDEA Method Validation Report.pdf)
- TEVA-MDL2875-00120889 (withheld document titled NDEA results of sartans.pdf)
- TEVA-MDL2875-00153996 (withheld document titled NDMA)
- TEVA-MDL2875-00171808 (withheld document titled NDMA - FOLLOW UP TO MAY 11 MTG)
- TEVA-MDL2875-00120882 (withheld document titled NDMA results of Sartans\_xlsx.pdf)
- TEVA-MDL2875-00040012 (withheld document titled NDMA Risk Assessment ME PTG.pdf)
- TEVA-MDL2875-00209262 (withheld document titled NDMA statement-TMS.pdf)
- TEVA-MDL2875-00110649 (withheld document titled Nitrosamine Questionnaire-Teva-Filled Questionnaire.pdf)
- TEVA-MDL2875-00074834 (withheld document titled Nitrosamines Steering Committee 13Dec19.doc)
- TEVA-MDL2875-00099046 (withheld document titled Nitrosamines Update -Jan 13 2020.pptx)
- TEVA-MDL2875-00163106 (withheld document titled Nitrosamines\_Questionnaire\_2019-11-18\_Actavis.pdf)
- TEVA-MDL2875-00443291 (withheld document titled Risk Assessment\_Valsartan\_NDMA\_NDEA.PDF)
- TEVA-MDL2875-00441836 (withheld document titled Risk from NDMA remains low, a related substance NDEA also being investigated.pdf)
- TEVA-MDL2875-00414483 (withheld document titled Toxicological Assessment for N-Nitrosodiethylamine (NDEA) in Valsartan 14Nov2018.pdf)
- TEVA-MDL2875-00414481 (withheld document titled valsaratan\_NDEA Evaluation-28112018.pdf)

**Documents about Valsartan**

- TEVA-MDL2875-00081768 (withheld document titled 02095\_AmlodValsHCTZ\_PiPPI\_E7\_15FPL.pdf)
- TEVA-MDL2875-00077404 (withheld document titled 02095\_AmlodValsHCTZ\_PiPPI\_E7\_15FPL.pdf)
- TEVA-MDL2875-00081769 (withheld document titled 02096\_AmlodValsHCTZ\_3PPI\_D7\_15FPL.pdf)
- TEVA-MDL2875-00103797 (withheld document titled 02 VALSARTAN STATMENT (ID-2895)-TIG.pdf)
- TEVA-MDL2875-00435185 (withheld document 066-CM-Valsartan hydrochlorothiazide rev B - Controlled Copy.pdf)
- TEVA-MDL2875-00324536 (withheld document titled 081718- Teva Valsartan HCTZ Tablets - Wholesaler and Retailer Recall Notices.pdf)
- TEVA-MDL2875-00164902 (withheld document titled 12534\_AMV\_Valsartan\_GCMS\_Protocol v1 -new..pdf)
- TEVA-MDL2875-00170802 (withheld document titled 174k0034-VALSARTAN-7611002016-41E255700.pdf)
- TEVA-MDL2875-00133709 (withheld document titled 2012-11 205210-1 ValasartanTabs,USP 40mg30s(LBL)VendorProof.pdf)
- TEVA-MDL2875-00133710 (withheld document titled 2012-11 205215-1 ValasartanTabs,USP 80mg1000s(LBL)VendorProof.pdf)
- TEVA-MDL2875-00156216 (withheld document titled 2012-12 208800 ValsartanTablets(PI)VendorProof.pdf)
- TEVA-MDL2875-00156215 (withheld document titled 2012-12 208801 ValsartanTablets(PatientInfo)VendorProof.pdf)

- TEVA-MDL2875-00399515 (withheld document titled 2017-05 Audit Report Request Valsartan.pdf)
- TEVA-MDL2875-00044997 (withheld document titled Vlasartan\_Mylan\_06.11.xlsx)
- TEVA-MDL2875-00138976 (withheld document titled VLN batches to Teva.pdf)
- TEVA-MDL2875-00135690 (withheld document titled Valsartan-VST Vs VAA-comparison.doc)
- TEVA-MDL2875-00441743 (withheld document titled VALSARTAN, ZHEJIANG HUAHAI PHARM.China, 01D\_C5523-16-084 0969-08.06.2016.pdf)
- TEVA-MDL2875-00290906 (withheld document titled Valsartan Update.pptx)
- TEVA-MDL2875-00350872 (withheld document titled Valsartan Update Meeting)
- TEVA-MDL2875-00441713 (withheld document titled VALSARTAN TIN FREE ZHEJIANG HUAHAI PHARM.China 01D\_C5523-17-182 1311 21.07.2017.pdf)
- TEVA-MDL2875-00183847 (withheld document titled Valsartan Timeline 10-23-12.pdf)
- TEVA-MDL2875-00101250 (withheld document titled Valsartan return to Huahai – Instructions)
- TEVA-MDL2875-00141673 (withheld document titled Valsartan Assessment report.pdf)
- TEVA-MDL2875-00461505 (withheld document titled Valsartan - HUAHAI 31-12-2018 - Q4\_18-2-2019\_FINAL02.xlsx)
- TEVA-MDL2875-00140418 (withheld document titled Valsartan - Huahai.pdf)
- TEVA-MDL2875-00430890 (withheld document titled Valsartan - customers notification- Azid process Jan2010.pdf)

**Documents about of Teva's Valsartan API Suppliers**

- TEVA-MDL2875-00137878 (withheld document titled “#177267\_Mylan Labs Ltd., Unit-VIII\_12th Nov 2018\_Audit Agenda.pdf”)
- TEVA-MDL2875-00446731 (withheld document titled 186960 - Zhejiang Huahai\_QTA-16 (Snezhana).pdf)
- TEVA-MDL2875-00268426 (withheld document titled 2012-07-16 Matrix name change to Mylan.pdf)
- TEVA-MDL2875-00112814 (withheld document titled 2018 -TSA-009 Site Risk Assessment Protocol - Zhejiang Huahai Pharmaceutical.pdf)
- TEVA-MDL2875-00407196 (withheld document titled 2018-GQ-019-1\_Zhejiang Huahai Pharmaceutical Co. Ltd \_Risk Assessment Pr....pdf)
- TEVA-MDL2875-00247578 (withheld document titled 2018-GQ-019\_Zhejiang Huahai Pharmaceutical Co. Ltd \_Risk Assessment Prot....pdf)
- TEVA-MDL2875-00367996 (withheld document titled 2018-GQ-019\_Zhejiang Huahai Pharmaceutical Co. Ltd \_Risk Assessment Protocol\_.pdf)
- TEVA-MDL2875-00367997 (withheld document titled 2018-GQ-019\_Zhejiang Huahai Pharmaceutical Co. Ltd \_Risk Assessment Protocol\_.xls)
- TEVA-MDL2875-00407194 (withheld document titled 2018-GQ-019\_Zhejiang Huahai Pharmaceutical Co. Ltd \_Risk Assessment Protocol\_CH.pdf)
- TEVA-MDL2875-00233488 (withheld document titled 2018-GQ-032\_Zhejiang Huahai Pharmaceutical Co. Ltd- Chuannan \_Risk Assessment Protocol\_.pdf)
- TEVA-MDL2875-00442024 (withheld document titled 2018-GQ-032\_Zhejiang Huahai Pharmaceutical Co. Ltd- Chuannan \_Risk Assessment Protocol\_.pdf)
- TEVA-MDL2875-00410075 (withheld document titled 2018-GQ-034\_Mylan - Andhra Pradesh \_Risk Assessment Protocol\_.pdf)
- TEVA-MDL2875-00414575 (withheld document titled 2018-GQ-034\_Mylan - Andhra Pradesh \_Risk Assessment Protocol\_.xls)
- TEVA-MDL2875-00279425 (withheld document titled 2018-GQ-034\_Mylan - Andhra Pradesh \_Risk Assessment Protocol\_signed.pdf)
- TEVA-MDL2875-00063200 (withheld document titled 2019-GQ-033\_Zhejiang Huahai Pharmaceutical Co Ltd ( Xunqiao site)- Assessment Protocol.pdf)
- TEVA-MDL2875-00415620 (withheld document titled 2019-GQ-033\_Zhejiang Huahai Pharmaceutical Co Ltd ( Xunqiao site)- Assessment Protocol\_.xls)

- TEVA-MDL2875-00398511 (withheld document titled Not acceptable suppliers - by Global QA (reviewed Igor 23.02.2015).xls)
- TEVA-MDL2875-00414647 (withheld document titled Note to File Mylan reaudit scheduled for July 1st 2019.docx)
- TEVA-MDL2875-00112717 (withheld document titled Zhejiang Huahai Pharmaceutical Co. Ltd-Chuannan \_Risk Assess.pdf)
- TEVA-MDL2875-00084964 (withheld document titled Zhejiang Huahai Chuannan China Request for Enhanced Supervision - Actavis Group PTC ehf.)
- TEVA-MDL2875-00148917 (withheld document titled Zhejiang Huahai Pharmaceutical Co. Ltd., Linhai, China 8.3.18 483\_FDA inspection.pdf)
- TEVA-MDL2875-00442002 (withheld document titled Zhejiang Huahai - NC letter with terms and conditions (Actavis).pdf)
- TEVA-MDL2875-00274899 (withheld document titled Zhejiang Huahai - NC letter with terms and conditions (Teva).pdf)

***Documents about inspections of Teva's Finished Dose Facilities where Valsartan was manufactured and/or tested:***

- TEVA-MDL2875-00446478 (withheld document titled 2012 Hal Far (Arrow) Malta FDA 483.pdf)
- TEVA-MDL2875-00446481 (withheld document titled 2010 Jerusalem OSD FDA 483 Response .pdf)
- TEVA-MDL2875-00446472 (withheld document titled 2011 Jerusalem FDA WL.pdf)
- TEVA-MDL2875-00171525 (withheld document titled 2015 Jerusalem OSD FDA 483 Response.pdf)
- TEVA-MDL2875-00400827 (withheld document titled 2015 Jerusalem OSD FDA 483 Response.pdf)
- TEVA-MDL2875-00171526 (withheld document titled 2015 Jerusalem OSD FDA 483.pdf)

The above-list is merely demonstrative and in no way meant to be exhaustive of all improperly withheld documents. Given the sheer volume of the universe of documents withheld as "Other Product(s)" (essentially 1 out of every 5 documents produced), Plaintiffs cannot (and should not) be required to go through and challenge each and every one of the 34,259 documents.

As such, Plaintiffs as Teva to re-produce these 34,259 documents marked as "Withheld – Other Product(s)" in full, and to do so immediately.

Plaintiffs are available to meet and confer with Teva prior to next week's Case Management Conference, such that the Parties can raise any outstanding issues regarding Teva's improper relevance review with the Court.

Best,

Layne

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